

1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

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5
6 IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

7 This document relates to:

8 THE COUNTY OF LAKE, OHIO,
9 et al. V. PURDUE PHARMA L.P., MDL No. 2804
et al., Case No. 18-op-45032

10 THE COUNTY OF TRUMBULL, OHIO, CASE No. 17-md-2804
11 et al., v. Purdue Pharma L.P.,
et al., Case No. 18-op-45079

12 Case Track 3

13 * * *
14

15
16 Remote Videotaped Deposition of
17 TREY EDWARDS, a witness herein, called by the
18 defendants for examination pursuant to the
19 Rules of Civil Procedure, taken before me,
20 Patti Stachler, RMR, CRR, a Notary Public
21 within and for the State of Ohio, at Mentor,
22 Ohio, on December 11, 2020, at 9:01 a.m.

23 * * *
24
25

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10 * * *

1 THE VIDEOGRAPHER: Today's date
2 is December 11, 2020. We're on the record at
3 9:01. This is the National Prescription Opiate
4 Litigation. The witness today is located in
5 Mentor, Ohio.

6 The court reporter may now swear
7 in the witnesses -- witness. All appearances
8 will be noted on the stenographic record.

9 TREY EDWARDS
10 a witness herein, having been first remotely duly
11 sworn as hereinafter certified, was examined and
12 deposed as follows:

13 EXAMINATION

14 BY MR. BARNES:

15 Q. Good morning, Mr. Edwards.

16 A. Good morning. How are you?

17 Q. I'm good. How are you?

18 A. Good.

19 Q. I can't see you, but I assume
20 that's a video issue. Mr. Edwards, would you
21 please state your full name and your address
22 listing city only, no street address?

23 A. Sure. My name is William John
24 Edwards. I go by Trey. I work for the State
25 of Ohio Board of Pharmacy in Columbus, Ohio.

1 Q. Mr. Edwards, do you go -- you said
2 you go by Trey. Is it okay if I call you Trey
3 during this?

4 A. Yes, absolutely.

5 Q. And you said you work for the Ohio
6 Board of Pharmacy, as in you're an agent; is
7 that your official title?

8 A. Correct.

9 Q. All right. So if I call you Agent
10 Trey, that's an accurate appellation?

11 A. Sure, yep. Just Trey is fine,
12 too.

13 Q. Trey, do you understand you're
14 appearing here pursuant to a notice of
15 deposition and a subpoena issued, and
16 acceptance of service was accepted by the Ohio
17 Board of Pharmacy on your behalf?

18 A. Yes.

19 Q. Did you receive this large binder
20 of exhibits at your home yesterday?

21 A. Yes. I have it right next to me.

22 Q. Okay. Were you able to take a
23 look at those exhibits to familiarize yourself
24 in any way with them, or are you looking at
25 them fresh? And, by the way, I was hoping that

1 you would take some time to look at them
2 because there are a lot of exhibits.

3 A. Yeah, I did look at them
4 yesterday.

5 Q. Okay. Would you take a look at
6 Exhibit 1? Is that the notice of deposition,
7 which you've seen before and for which you're
8 appearing today?

9 A. Yes.

10 Q. Okay. Have you ever been deposed
11 before, Mr. Edwards?

12 A. I have not.

13 Q. Have you ever testified before? I
14 assume, as an agent, you've testified probably
15 dozens of times?

16 A. Yes, many times.

17 Q. Okay. But in a civil deposition,
18 just to familiarize yourself with the process,
19 this is a remote deposition, and so we're all
20 experiencing something new. But what will
21 happen is, I will ask the questions, give me
22 time to ask the question. You'll get a full
23 opportunity to answer. Make sure you hear and
24 understand my questions or ask to have it
25 repeated. Otherwise, if you don't ask any

1 questions, I'll -- about my question, I'll
2 assume you fully understood it and are giving
3 your most truthful responses. Is that agreed
4 to?

5 A. Yes.

6 Q. And I'll just remind you that
7 because there's a court reporter, you need to
8 give verbal responses. She may not pick up
9 shakes of the head or any other physical cues
10 because of the video process. So be sure to
11 make verbal responses. And if you need a break
12 at any time, just let me know, and we'll take a
13 break.

14 A. Okay.

15 Q. Let me know at any time if you
16 have any technical difficulties, if it cuts
17 out, or if you can't hear us or you need to
18 reconnect, anything like that.

19 Under the protocol entered in this
20 case, other than communications with your counsel,
21 there's to be no texting or emailing or anything
22 related to your testimony during the course of the
23 deposition. Do you understand that?

24 A. Yes.

25 Q. Okay. Are you physically alone

1 for this deposition today?

2 A. Yes.

3 Q. Okay. Have you had an opportunity
4 to prepare for your deposition by talking with
5 your counsel, Mr. Appel, or any other lawyers
6 at the Ohio Board of Pharmacy?

7 A. Yes.

8 Q. All right. Were you able to
9 review documents and discuss the issues that
10 you might testify about?

11 A. Yes.

12 Q. Approximately how long did you
13 prepare for your deposition in that regard?

14 A. Oh, a couple days. I would say
15 ten, 12 hours, something like that.

16 Q. Okay. Were you able to refresh
17 your recollection as to your involvement with
18 the inspections of Giant Eagle Pharmacies and
19 other pharmacies that are involved in this
20 case?

21 A. Yes.

22 Q. Have you had any contact at all
23 with lawyers other than the Ohio Board of
24 Pharmacy related to your testimony today?

25 A. Yes, I have.

1 Q. Who have you had contact with?

2 A. Frank Gallucci and the
3 gentlemen -- the two gentlemen that he's
4 working with who represent Lake County.

5 THE VIDEOGRAPHER: Sorry. Can we go
6 off the record for one second, please?

7 (Off the record.)

8 THE VIDEOGRAPHER: We're on the
9 record, 9:07.

10 BY MR. BARNES:

11 Q. All right. Mr. Edwards, we're
12 back on the record. When we broke for a
13 minute, you were telling me that you have had
14 contact with Frank Gallucci and two other
15 gentlemen representing Lake County?

16 A. Correct.

17 Q. Do you remember the two other
18 gentlemen's names?

19 A. I do not. They were told to me.
20 I was told one would be on the call today.
21 They represent -- they represent Lake County,
22 and I used to work for Lake County, so that's
23 their involvement, but I don't recall the other
24 two gentlemen's names.

25 Q. Okay. And when did you meet with

1 them and for how long?

2 A. I talked on the phone with Frank,
3 oh, probably about an hour -- 45 minutes to an
4 hour with the three of them the other day, and
5 then previously I have talked to
6 Mr. Gallucci -- we did like a Zoom call for
7 probably another hour.

8 Q. And were your conversations in
9 connection with your prior employment at Lake
10 County?

11 A. Yes.

12 Q. Did the conversations involve
13 anything related to your current employment at
14 the Ohio Board of Pharmacy?

15 A. No.

16 Q. Can you give us a little summary
17 of your educational background? I've seen it
18 in some documents, but starting with college.
19 What was your degree, from where, and what
20 year?

21 A. Sure. Criminal -- I majored in
22 criminal justice at Ohio State. I graduated in
23 1998. After that, I went to the police academy
24 in Cleveland Heights, and that was a class of
25 '99, and then started to work for Lake County

1 in 2000.

2 Q. Okay. Do you have any other
3 formal education other than your BA in criminal
4 justice?

5 A. No.

6 Q. Master's degree, course work,
7 anything like that?

8 A. No.

9 Q. Do you have any professional
10 certifications or testing that is -- I'll just
11 leave it at that.

12 A. I'm a certified peace officer with
13 the State of Ohio.

14 Q. What do you have to do to become a
15 certified peace officer?

16 A. Go through the police academy and
17 just maintain the continuing education
18 requirements that they set.

19 Q. All right. What was your first
20 job? You said you went to the police academy,
21 you came out in '99, and your first job was
22 with Lake County, 2000?

23 A. Yes. Lake County Narcotics
24 Agency. I began there in 2000.

25 Q. And what was your position there?

1 A. The title was special agent; more
2 specifically, I was a pharmaceutical diversion
3 investigator.

4 Q. Did you go through training to
5 become a pharmaceutical diversion investigator
6 for Lake County?

7 A. Prior to getting hired, no, just
8 the police academy.

9 Q. But how about after getting hired?

10 A. Afterward, I did various classes,
11 DEA-sponsored drug investigation classes and
12 the National Association of Drug Diversion
13 Investigators, I've been to a number of their
14 trainings.

15 Q. Okay.

16 A. Mostly on-the-job training.

17 Q. And in this training, including
18 on-the-job training, did you become familiar
19 with Ohio law and federal law related to
20 pharmaceutical diversion?

21 A. Yes.

22 Q. Okay. And were you -- how long
23 were you a special agent for the Lake County
24 Narcotics Agency?

25 A. So till 2008. I began with the

1 State of Ohio in November of 2008.

2 Q. You mean you started with the Ohio
3 Board of Pharmacy in November of '08?

4 A. Correct.

5 Q. And for the 2000 through 2008 time
6 period, were you always a special agent with
7 the pharmacy diversion investigative unit of
8 the Lake County Narcotics Agency?

9 A. Yes.

10 Q. What were your duties as a special
11 agent?

12 A. To investigate drug laws. We were
13 a unique agency. We were a law enforcement
14 agency; however, our arrest powers only had to
15 do with drug laws of the State of Ohio. So I
16 enforced the drug laws, particularly Ohio
17 Revised Code 2925.22 and 2925.23. Those are
18 the main two sections of law that we focused
19 on, but there were others as well.

20 Q. Did you actually use those powers
21 from time to time to arrest for violation of
22 the drug laws?

23 A. Yes.

24 Q. Those are references to the Ohio
25 Revised Code; is that correct?

1 A. Correct.

2 Q. Okay. When working in law
3 enforcement as a special agent with -- I'll
4 call it LCNA for short.

5 A. Sure.

6 Q. -- with LCNA, did you have a
7 partner or did you work on a team --

8 A. Yes.

9 Q. -- or did you do primarily
10 individual investigations?

11 A. When I started, I had two
12 partners, and they -- throughout my time there,
13 they both then retired and hired in somebody
14 else, then I had one partner.

15 Q. Who were your two partners and
16 then the one partner?

17 A. The initial partners were Jim
18 Snyder and Judy Pugh. P-u-g-h is her last
19 name. And they were there till, I want to say,
20 around 2003 or so. And then Chris Begley was
21 hired in -- I believe in 2003, and he was my
22 partner from 2003 until 2008.

23 Q. And you would investigate pharmacy
24 diversion matters as a team?

25 A. Yes.

1 Q. Did you do primarily criminal, or
2 did you do both criminal and civil?

3 A. All criminal. Exclusively
4 criminal.

5 Q. All criminal. Okay.

6 A. Yeah.

7 Q. Did you have any -- do you recall
8 any notable criminal prosecutions that you had
9 while an LCNA agent?

10 A. I mean, not any that stand out,
11 but, yeah, many. I mean, we would probably
12 have 50 to 60 cases a year between myself and
13 my partners.

14 Q. And were they -- you said you were
15 in the pharmacy diversion investigative unit.
16 Who were you primarily prosecuting in that time
17 period?

18 A. Primarily the general public. The
19 vast majority of cases we had were around the
20 general public.

21 Q. And what types of crimes were they
22 committing while you were an agent?

23 A. The two ORC codes that I
24 mentioned, basically in laymen's terms, doctor
25 shopping and illegal processing were the two

1 crimes, people writing bad prescriptions,
2 forging prescriptions, and then doctor
3 shopping, seeing multiple doctors to obtain
4 overlapping prescriptions.

5 Q. And did you --

6 MR. APPEL: Can I interrupt for a
7 moment? This is Henry Appel. May we go off
8 the record for about one or two minutes for me
9 to take care of a quick personal matter that I
10 mentioned to you before the hearing began?

11 MR. BARNES: Yes, that's fine.

12 THE VIDEOGRAPHER: Off the record
13 9:15.

14 (Off the record.)

15 THE VIDEOGRAPHER: We're on the
16 record at 9:17.

17 BY MR. BARNES:

18 Q. Okay. Mr. Edwards, we're back on
19 the record. We were talking about doctor
20 shopping, and I think the term you used was
21 illegal prescriptions?

22 A. Illegal processing.

23 Q. Illegal processing. What do you
24 mean by that?

25 A. When somebody forges a

1 prescription either by altering what a doctor
2 already wrote or by creating their own false
3 prescription.

4 Q. I see. While you were an agent
5 with LCNA, did you work with the local
6 pharmacies as part of your investigations?

7 A. Yes, routinely.

8 Q. And can you describe that for us?
9 How would you work with the local pharmacies?

10 A. Well, the vast majority of our
11 complaints came in through the pharmacies. We
12 would do -- we would do visits. We called them
13 inspections but they weren't really
14 inspections. They were more or less, you know,
15 PR visits that -- just talk to the pharmacists,
16 get to know them and, you know, let them know
17 what kind of things we were seeing in the area
18 and what to look out for.

19 We would have -- we would host
20 continuing education forums with them so that
21 they could get law CEs where we would tell
22 them, again, what we were seeing, what trends
23 we were seeing, what to look for. It was
24 pretty much a daily basis where we would have
25 dealings with the local pharmacists.

1 Q. I forgot to mention to you that I
2 represent Giant Eagle.

3 A. Okay.

4 Q. And the other defendants in this
5 case are CVS, Walgreens, Rite-Aid, and Walmart.
6 So along with those four, along with Giant
7 Eagle, I'll sometimes call them the pharmacy
8 defendants --

9 A. Okay.

10 Q. -- just for ease of reference.

11 Do you recall working with
12 pharmacists employed by the pharmacy defendants
13 when you were at LCNA?

14 A. Yes.

15 Q. And specifically, do you remember
16 working with Giant Eagle pharmacists in
17 diversion investigations?

18 A. Yes.

19 Q. As well as CVS, Walgreens,
20 Rite-Aid, and Walmart pharmacists?

21 A. Yes.

22 Q. These pharmacists, in your
23 recollection, who work for the pharmacy
24 defendants, were they helpful in your
25 investigations and cooperative and assist you

1 in any way they could to prevent diversion?

2 A. Yes.

3 Q. In what ways would they assist
4 specifically? What would you need from the
5 pharmacists? You said that the majority of
6 complaints came from the pharmacists. What
7 were the nature of those complaints and how
8 would they assist after making the complaint?

9 A. Well, we --

10 MR. CIACCIO: Objection to form.

11 A. So your question was, how did the
12 pharmacists assist us?

13 BY MR. BARNES:

14 Q. Yeah. I was referring back to
15 your testimony a couple minutes ago. You said
16 that the majority of the complaints when you
17 were an agent at LCNA came from the
18 pharmacists?

19 A. Correct. Yeah, so essentially, if
20 someone came into their pharmacy with a bad
21 prescription or raised any sort of red flags
22 like from out of the area or, you know, a high
23 dose or just something that raised their
24 suspicion, they would call.

25 If we -- essentially the way we

1 operated, it was somewhat routine in that we
2 would develop a list of suspects who we had
3 received calls about and we would send that out
4 to the pharmacies. We didn't have OARRS -- the
5 Ohio Automated Rx Reporting System back then,
6 so the description history of individuals was
7 not at our fingertips like it is today, so we
8 would have to compile a list, send it out to
9 the pharmacies, and ask them, you know, if they
10 had seen those people, if they had had dealings
11 with them, and then they would report back to
12 us.

13 So there were many -- many reasons
14 that they would call us just to ask a question
15 or to report what they thought might be a crime
16 or to just maybe ask -- you know, ask about an
17 individual or a prescriber or, you know, a
18 general question.

19 Q. I see. So you would be getting
20 information from pharmacists, they would see
21 suspicious behavior in the pharmacies for any
22 number of reasons. And from that information,
23 is that where you would create the list?

24 A. For the most part, yeah.

25 Q. Okay. And then you would

1 disseminate that list to all of the other
2 pharmacies in Lake County?

3 A. Correct, we would either mail it
4 or fax it out and basically ask them, has this
5 person been in your store, is there anything,
6 you know, that happened that you could tell us
7 that, you know, would be beneficial for our
8 investigation. And, you know, sometimes there
9 was nothing, sometimes there was a good case
10 and they were going to several pharmacies in
11 the area.

12 Q. I see. So this was pre OARRS?

13 A. Correct.

14 Q. Did the pharmacies respond to
15 those lists from time to time and tell you
16 things that would assist?

17 A. For the most part. The way -- the
18 way we worded it, I believe, was if this person
19 has been in your pharmacy, please let us know.
20 So we wouldn't hear from every pharmacy every
21 month because if they didn't have any of those
22 people in their store, they wouldn't call. But
23 if they ran their -- you know, checked the
24 names in their profile and they were there and
25 there was something that they thought they

1 should share with us, they would call.

2 Q. I see. And from time to time
3 would you ask for further information from the
4 pharmacies, things like, give us copies of all
5 your prescriptions for this individual, things
6 of that nature?

7 A. Yes. Most commonly we would ask
8 for what was called the prescription profile,
9 and that was essentially the year's worth of
10 prescriptions that they filled.

11 Q. Did you do pharmacy inspections
12 while you were an agent with LCNA?

13 A. We called them inspections, but
14 they -- like I said, they weren't really
15 inspections, they were more or less PR visits
16 where we'd go in and we'd, you know, ask them
17 how many prescriptions they were filling and,
18 you know, just general -- general questions.

19 We called them inspections back
20 then. And had you asked me back then, I would
21 say, yeah, we do inspections. But now, having
22 worked for the Board of Pharmacy, I realize
23 what we did at Lake County Narcotics was
24 nothing even close to an inspection.

25 Q. I see. And we'll get to that and

1 have a good point to compare.

2 A. Sure.

3 Q. Who did you report to at LCNA
4 while an agent?

5 A. My direct supervisor initially was
6 Ed Ebert. He was lieutenant. And my -- the
7 executive director was Chris Collins initially
8 and then John Germ. So there were two
9 executive directors in my time there.

10 Q. While you were an agent for LCNA,
11 were you -- and doing your investigations and
12 prosecutions, were you able to learn about the
13 nature of pharmaceutical diversion in Lake
14 County in that time period, 2000 through 2008?

15 A. Yes.

16 Q. Did you come to understand at any
17 time as an agent that Lake County was
18 experiencing pharmaceutical diversion coming
19 into the county from outside the county?

20 A. Well, I didn't specifically notice
21 that trend standing out. I mean, we had cases
22 all the time where people would be from
23 Cuyahoga County or people would be from another
24 area and come into our county. We always said,
25 you know, criminals don't know county

1 boundaries. So often there were cases that
2 extended into other areas or came into our
3 area.

4 Q. When you use the term diversion,
5 are you using it in the context of
6 pharmaceutical diversion, or are you --

7 A. Pharmaceutical diversion. When
8 prescription drugs go out of the legitimate
9 channels.

10 Q. And the legitimate channel would
11 be, I guess, manufacturer to distributor to
12 pharmacy to patient; is that correct?

13 A. Yes.

14 Q. Are there different forms of
15 pharmaceutical diversion, in your experience?

16 A. Sure.

17 Q. Can you tell us what that is?

18 A. Well, it can take many forms. It
19 can be theft. It can be forging prescriptions.
20 It can be trafficking. It can be misuse or
21 abuse. It can be tampering. It can be -- I
22 mean, there's -- any way you can take a
23 pharmaceutical drug and take it out of that
24 legitimate channel is -- would be diversion.

25 Q. I see. Okay. Well, that's

1 helpful to get that explanation. Did you
2 investigate thefts of pharmaceuticals while an
3 agent with LCNA?

4 A. I don't recall any specific theft
5 case. I believe I probably did, but I don't
6 recall any off the top of my head. I remember
7 getting calls about patients saying someone
8 stole my prescriptions and stuff like that, but
9 I don't recall if they developed into a case
10 or, you know, someone was prosecuted. That
11 type of investigation I handled much more
12 frequently in my current job than I did at Lake
13 County.

14 Q. Okay. When you say theft, are you
15 including things like a pharmacy tech stealing
16 pills or are you more --

17 A. Yes. Well, both. I mean, now
18 that we're sitting here, I am recalling a case
19 of an individual stealing drugs from the
20 patient who had the prescription. And I can
21 recall another case where I worked it with the
22 state pharmacy board of a technician who was
23 stealing drugs --

24 Q. Okay.

25 A. -- in Lake County.

1 Q. All right. And as an agent with
2 LCNA, did you investigate forged prescriptions?
3 And that would be criminals forging doctors'
4 prescriptions and trying to get them filled at
5 pharmacies.

6 A. Yes. That was a very common crime
7 that we investigated.

8 Q. And trafficking, what do you mean
9 by trafficking?

10 A. Selling. Selling drugs.

11 Q. And that would be outside the
12 closed system we talked about?

13 A. Correct. Yes.

14 Q. And did you prosecute those kinds
15 of cases -- investigate and prosecute those
16 kinds of cases in Lake County?

17 A. Occasionally. Not as commonly as
18 the forging prescriptions or the doctor
19 shopping, but occasionally we would have
20 trafficking cases. A lot of times those
21 cases -- the way Lake County operated, we had
22 the pharmaceutical diversion agents and then we
23 had another group, an enforcement group, who
24 basically worked at night. When I was there,
25 it was like a 4:00-to-midnight shift, and they

1 did the street drugs. So when the
2 pharmaceutical cases would go to the street
3 side and involve trafficking and stuff like
4 that, a lot of times that group would handle
5 those cases.

6 Q. I see. You also mentioned
7 tampering and there was another category. I
8 scribbled it so fast, I can't read my own
9 handwriting. Is it misuse and abuse? Is that
10 what you said?

11 A. Yes.

12 Q. Okay. And what is -- what types
13 of prosecutions are those?

14 A. Tampering would be like a nurse at
15 a nursing home stealing the patient's Percocet
16 and replacing it with Tylenol or diluting an
17 injectable medication so it's not the same
18 strength as what the doctor prescribed.

19 Q. I see. And what is misuse and
20 abuse? What does that mean?

21 A. That's -- that would be somebody
22 overusing their medications; maybe they have a
23 legitimate prescription, they're supposed to
24 take two or three and they take six or eight or
25 they -- it leads -- often leads into doctor

1 shopping because --

2 Q. I see.

3 A. -- what their current doctor's
4 giving them isn't enough, so then they need
5 more.

6 Q. I see. And did you do those types
7 of investigations and prosecutions while an
8 agent with LCNA?

9 A. We did the doctor shopping
10 investigations. I mean, misuse of a prescribed
11 drug is not in and of itself a crime.

12 Q. Okay. Are the methods -- in your
13 experience, are the methods that individuals
14 use to divert prescription drugs, do they
15 change over time, particularly in response to
16 law enforcement efforts?

17 A. Of course, yes.

18 Q. Can you give me an example of
19 that?

20 A. Well, doctor shopping would be an
21 example. Back before we had OARRS, it was much
22 easier for someone to go to multiple pain
23 management doctors and get overlapping
24 prescriptions, whereas now it's much more
25 difficult because the information that was not

1 available back then is at their fingertips
2 right now.

3 Q. I see. In your experience as an
4 agent and also as an agent with the Board of
5 Pharmacy, do your investigations sometimes
6 involve criminal organizations that are
7 expressly working with prescription drugs and
8 diverting prescription drugs?

9 A. Occasionally.

10 Q. Okay.

11 A. Define organization.

12 Q. Yeah, I understand. I'm a former
13 prosecutor myself, so --

14 A. You mean the group?

15 Q. Yeah.

16 A. If you mean a group of people
17 acting together for the same goal, then, yes.
18 If you mean a formal organization with a
19 president and vice president, something like
20 that, then no.

21 Q. No, no. That's not what I meant.
22 I meant, you know, people engaged in
23 conspiracies to divert.

24 A. Yes. Yes. People working
25 together and -- yes.

1 Q. Is that something that you saw in
2 Lake County when you were with LCNA?

3 A. Yes. Yes. Like multiple
4 people -- for instance, if someone stole a
5 prescription pad and had friends or associates
6 that then would go fill the prescriptions and,
7 you know, sell them back or share or whatever,
8 like that type of thing. Or more recently --
9 are you just referring to my time in LCNA or --

10 Q. Yes. But I would naturally expand
11 it if you feel like you have some relevant
12 information.

13 A. Well, recently there's issues with
14 promethazine with codeine, cough syrup, and
15 there's groups -- there's organizations that
16 travel throughout the country breaking into
17 pharmacies and either stealing it or forging
18 prescriptions to get it. So, yes, there are
19 groups out there who commit diversion together.

20 Q. Okay. The people that you've
21 investigated, including doctor shoppers and
22 criminals, are they individuals who engage in
23 deceptive activity with doctors and
24 pharmacists?

25 A. Sure. Yes.

1 Q. Do your investigations -- or did
2 your investigations involve multiple agencies
3 like local police, FBI, DEA, and other law
4 enforcement agencies?

5 A. Occasionally.

6 Q. Have you ever worked on a task
7 force where you have multiple agencies coming
8 together to investigate pharmaceutical
9 diversion?

10 A. I've never been assigned to a task
11 force. I've worked with task forces.

12 Q. Which task forces have you worked
13 with?

14 A. I've -- well, when I say worked
15 with, I'm referring to working a case with and
16 I'm also referring to collaborating with to get
17 information.

18 Q. Okay.

19 A. So I've worked with the West Shore
20 Enforcement Bureau, the SEAL Task Force, the
21 TAG -- I don't believe it's called TAG anymore,
22 but Trumbull Ashtabula Group, Mahoning Valley
23 Drug Task Force. There may be others. That's
24 all I can think of for the moment.

25 Q. What was the first one you

1 mentioned? I didn't catch that name.

2 A. The West Shore Enforcement Bureau.

3 Q. West Shore. Okay.

4 A. Yeah, they're in Cuyahoga County.

5 Q. And are all these task forces
6 essentially in the northeastern corridor of
7 Ohio?

8 A. Essentially, yes.

9 Q. Okay. The investigations -- some
10 of your investigations, did they take long
11 periods of time; years, for example, from start
12 to finish?

13 A. With the Pharmacy Board, yes.
14 With Lake County, I don't recall any taking
15 years. They may have. From start -- from
16 initial complaint to criminal resolution,
17 probably.

18 Q. In your work as an agent with LCNA
19 and now as an agent for the Board of Pharmacy,
20 have either of those agencies been able to
21 totally stamp out pharmaceutical diversion by
22 criminals and others?

23 A. No.

24 Q. You mentioned the National
25 Association of Drug Diversion Investigators.

1 Are you a member of that organization?

2 A. Yeah, I am. I'm the state vice
3 president.

4 Q. What does that organization do
5 primarily?

6 A. Primarily training and networking
7 of individuals who work in the field of
8 pharmaceutical diversion.

9 Q. All right. I want to shift focus
10 now and talk about the State Board of Pharmacy.
11 You said you went to work for the State Board
12 of Pharmacy in November of 2008?

13 A. Correct.

14 Q. And your first position there was
15 as an agent?

16 A. Correct.

17 Q. And were you an agent in a
18 specific division of the Board of Pharmacy?

19 A. No. I was just a general
20 compliance agent.

21 Q. What does that mean to be a
22 general compliance agent?

23 A. Just a -- we have different --
24 well, at the time I was hired, we had two
25 different types of enforcement employees. It

1 would be the agents like myself who primarily
2 came from law enforcement backgrounds, and then
3 we had specialists who were pharmacists. They
4 didn't have law enforcement backgrounds. They
5 were clinical or, you know, or retail
6 pharmacists in their background.

7 Q. So you had -- they were called
8 agents and specialists?

9 A. Correct.

10 Q. Did the agents and specialists
11 work together on the pharmaceutical diversion
12 investigations?

13 A. Yes.

14 Q. And have you always been an agent
15 since November of '08 through today?

16 A. Yes.

17 Q. And have you always reported to
18 the same individual in that 12-year time
19 period?

20 A. No. My supervisors have changed
21 quite a bit.

22 Q. Who's your current supervisor?

23 A. Kevin Flaharty.

24 Q. Do you remember any prior
25 supervisors?

1 A. Prior to Kevin, it was Tom Pyles.
2 Prior to Tom, it was Lisa Dietsche. Prior to
3 Lisa Dietsche, it was Jim Reye. And he was --
4 he was my first supervisor when I started.

5 Q. Were you when you first went to
6 work for the Board, were you assigned to a
7 particular geographic area of Ohio?

8 A. Yes. The northeast.

9 Q. What does the northeast area
10 encompass?

11 A. Well, it's changed over the years.
12 When I was hired, it encompassed Lake, Geauga,
13 Portage, Ashtabula, and at different times I
14 had parts of Cuyahoga, parts of Summit, parts
15 of Medina. So it's basically the northeast
16 corner of the state, but those initial counties
17 that I mentioned were where I primarily worked.

18 Q. I see. And you didn't mention
19 Trumbull. Has Trumbull been in your area of --

20 A. I've worked in Trumbull. I've
21 never -- I don't believe I was ever assigned
22 Trumbull, to my recollection. But I have
23 worked occasionally in Trumbull County.

24 Q. Are there other agents assigned to
25 Trumbull County?

1 A. Yes.

2 Q. Who are they?

3 A. Currently, I believe Bill
4 DiFrangia is the agent for that area.

5 Q. What about George Pavlich, do you
6 recognize that name?

7 A. Yes, he was with the agency when I
8 was hired, but he retired I believe in 2012.

9 Q. Did he do Trumbull County?

10 A. Yes. He had the Youngstown area,
11 so Trumbull, Mahoning, Columbiana, those
12 counties.

13 Q. So how would you describe the
14 responsibilities as an agent with the Ohio
15 Board of Pharmacy?

16 A. My responsibilities are to
17 investigate criminal allegations that are
18 violations of the Ohio Revised Code, Ohio
19 Administrative Code, and the Code of Federal
20 Regulations, as well as an administrative
21 component where we do inspections of facilities
22 that manufacture, store, sell, distribute
23 dangerous drugs.

24 Q. That's a general description for
25 all 12 years of your experience as an agent at

1 Ohio Board?

2 A. Generally. Most recently, for the
3 past three years, I've been working on an early
4 intervention grant. So I've -- for the past
5 three years, I have not -- I still do those
6 things, but not as much as the intervention
7 component.

8 Q. Okay. And were you trained when
9 you arrived at the Board of Pharmacy? Were you
10 given specific training either before or after
11 you arrived with respect to the Ohio Revised
12 Code and the Administrative Code?

13 A. Yes. I was -- I went through some
14 training with the local agents in the northeast
15 and basically shadowed them for a period of
16 time. I don't remember how many weeks.

17 Q. Were you at any time given copies
18 of the Ohio Revised Code or Administrative Code
19 to review --

20 A. Yes.

21 Q. -- the provisions, become familiar
22 with them?

23 A. Yes. We were given the book. You
24 know, back then, it was like a phone book in
25 size; kind of like this book of exhibits here.

1 Q. Okay. So you've seen them before?

2 A. Yes.

3 Q. And you've provided training, or
4 have you provided training as I guess a more
5 senior agent now at the board, do you train
6 younger agents?

7 A. I have; not recently, but I did
8 spend a number of years training other agents.

9 Q. Did you specifically provide
10 training with respect to the OARRS program?

11 A. No. Well, I take that back. I
12 provided training to law enforcement about the
13 OARRS program, but I did not provide training
14 to our agents about the OARRS program.

15 Q. How long -- in what time period
16 did you provide training -- OARRS training to
17 law enforcement?

18 A. Oh, probably five or six years
19 ago. It was a short-lived program. It was --
20 law enforcement was -- my recollection is law
21 enforcement was having issues with OARRS and we
22 were trying to increase the amount of use by
23 law enforcement. So we developed this
24 PowerPoint program to present to law
25 enforcement and the response was not very good.

1 So we ended up -- not me, but we meaning our
2 agency, created an online training program for
3 OARRS to replace the in-person training.

4 Q. So how long did that OARRS
5 training last? It sounds like it was just a
6 short time period?

7 A. It was short. I want to say less
8 than a year, and I think we only did a handful
9 of those trainings.

10 Q. Okay. I'll get to -- you may have
11 seen in the binder I sent you --

12 A. Yes.

13 Q. -- there was one of your training
14 sessions. We'll get to that.

15 A. Okay.

16 Q. The Board of Pharmacy, what is its
17 role in Ohio with respect to regulating the
18 pharmacy industry and investigating civil and
19 criminal violations?

20 A. Well, it has a component where
21 there's licensing. We administer licenses to
22 the entities that manufacture, store,
23 distribute, sell drugs. So we have the
24 licensing aspect, the administrative aspect
25 where we enforce the rules of the Ohio

1 Administrative Code, and then the law
2 enforcement aspect where we enforce the
3 criminal rules or the criminal laws of the Ohio
4 Revised Code and CFR.

5 Q. Would you take a look at Exhibit 2
6 in the binder that I sent you?

7 A. Yes.

8 MR. BARNES: And, Clint, if you
9 could pull up the exhibit, Exhibit 2, Edwards
10 Exhibit 2.

11 MR. THOMAS: Yes, working on it now.

12 BY MR. BARNES:

13 Q. Mr. Edwards, have you seen this
14 document before called the Role of the Ohio
15 State Board of Pharmacy/OARRS?

16 A. I see it here in the book. I
17 don't -- I don't recall whether or not I was at
18 that particular NADDI training where this
19 presentation was given, but I may have been.

20 Q. Flip to page 4, please. There's a
21 page number in the bottom right. Page 4.
22 There's a description, it's called the Role of
23 the Board. If the Board is charged with
24 enforcing key chapters of the Ohio Revised
25 Code, including drug offenses, pure food and

1 drug laws, controlled substances and
2 pharmacists, dangerous drugs.

3 Does that seem correct to you that
4 that's the role of the Board of Pharmacy to
5 enforcing these Ohio laws?

6 A. Yes.

7 Q. Okay. Is it missing anything that
8 you can think of?

9 A. Not that I can think of.

10 Q. On the next page it breaks the
11 Board down into administrative, communication
12 and education, and law enforcement. You seem
13 to have kind of done that on your own.
14 Licensing and regulating pharmacists, pharmacy
15 interns, and locations that store dangerous
16 drugs, pharmacies, EMS, physician's offices,
17 and wholesalers. That's the administrative
18 side?

19 A. Yes, correct.

20 Q. And then there's communication and
21 education, legislative affairs, stakeholder
22 outreach, training, and operation OARRS, Ohio's
23 prescription drug database. That's the
24 communication and educational side?

25 A. Yes.

1 Q. Is that right? And, finally, law
2 enforcement enforcing the drug laws.

3 Now, just to finish, there's an
4 agency structure on page 6 breaking the agency
5 down into multiple sections, licensing, legal
6 affairs, policy and communication, compliance and
7 legal, the OARRS department. Does that comport
8 with your understanding of how the Board is
9 structured?

10 A. Yes.

11 Q. And then on the seventh -- pages 7
12 through 9 seems like you anticipated some of
13 the questions I would have. This appears to
14 break down the staff between agents and
15 specialists. You already told us about that?

16 A. I didn't anticipate it. I just am
17 used to being asked that in court, so --

18 Q. Okay. There's a -- with respect
19 to specialists, you told us these are licensed
20 pharmacists who assist in investigations; is
21 that right?

22 A. Correct.

23 Q. And do they tend to do the more
24 complex investigations?

25 A. They tend to do the investigations

1 that involve practice-related issues or, like
2 you said, more complex drug issues such as
3 compounding.

4 Q. Okay. Page 10 of this exhibit
5 lists the criminal investigations, drug
6 diversion. You also have already covered some
7 of this: theft, tampering, deception to obtain
8 the dangerous drugs, illegal processing of drug
9 documents.

10 Is that a general description of what
11 the criminal agents do at the Board, including
12 yourself?

13 A. Yes.

14 Q. Now, the pages 11 through 24 of
15 this exhibit give a description of OARRS. Now,
16 that's the PDMP program started by Ohio in
17 about 2006; am I correct?

18 A. Correct, yes.

19 Q. And what do you recall was the
20 main reason behind OARRS and its main purpose?

21 A. To give pharmacists, prescribers,
22 and law enforcement quicker access to
23 information related to prescriptions being
24 written to help to stem the drug abuse or the
25 drug opiate epidemic.

1 Q. Was it specifically designed for
2 the opiate epidemic?

3 A. I don't recall its specific reason
4 for being designed. I just know that that's
5 what it helped.

6 Q. Okay. Prior to the creation of
7 OARRS, you had told us in your investigations
8 as an agent with LCNA that you really didn't
9 have a database to go to so you created lists
10 by talking to pharmacists and getting input
11 from pharmacists. Is that -- did OARRS
12 basically replace that --

13 A. Yes.

14 Q. -- that system?

15 A. Yes. It made a month-long
16 investigative inquiry into a few-minute-long
17 inquiry.

18 Q. Okay. So am I correct that once
19 OARRS was formed, pharmacies were required to
20 report to the Board of Pharmacy through the
21 OARRS system each and every prescription filled
22 at the pharmacy on a day-to-day basis?

23 A. Not every prescription; just
24 controlled substances.

25 Q. Controlled?

1 A. Mainly controlled substances. At
2 one time or another, there were a few other
3 drugs that were not controls but were reported
4 such as tramadol and gabapentin.

5 Q. And from day one, was that on a
6 daily basis, or did it start on a different
7 periodic reporting format, you know --

8 A. I don't believe it was daily to
9 start. I believe it was -- I don't believe --
10 I don't remember what the requirement was, but
11 I believe it was a few days. And then it
12 became 24 hours, they had to report within 24
13 hours. And --

14 Q. Okay. And what about doctors who
15 filled prescriptions in their offices, did they
16 have to similarly report to OARRS drugs they
17 were giving out in their office?

18 A. I don't recall if that was an
19 initial requirement, but it is now.

20 Q. Okay.

21 A. I believe it was, but I don't
22 recall.

23 Q. On pages 14 and 15 of this
24 Exhibit 2, there's a discussion of when a
25 pharmacist must query OARRS. Now, this

1 document I believe is approximately
2 September 25th of 2017. So as of September of
3 2017, does this refresh your recollection as to
4 when a pharmacist must query OARRS?

5 A. Yes.

6 Q. On page 14? When a patient adds a
7 different or new controlled substance to their
8 therapy that was not previously included or an
9 OARRS report has not been reviewed for that
10 patient during the preceding 12 months, as
11 indicated in the patient profile, or if a
12 prescriber is located outside the usual
13 pharmacy geographic area.

14 Was that in OARRS from day one, or
15 was there a period of time when OARRS was a
16 discretionary access and then it became
17 mandatory under certain conditions?

18 A. Yeah, that's correct.

19 Q. Do you recall when it became
20 mandatory when these types of conditions
21 occurred? Was that in or around -- well, I'll
22 ask you. I'm not going to suggest a day.

23 A. Going by this presentation, it
24 says effective February 1st, 2016. So I --

25 Q. Oh, okay.

1 A. I'll go by that. I don't recall.

2 Q. Okay. So for about ten years, I
3 guess, January 1st of '06 until about
4 February 1 of '16, it was up to the pharmacist
5 to determine whether it was going to -- he or
6 she was going to access OARRS, and then as of
7 about February 1 of 2016, it became mandatory
8 if one or more of these conditions occurred?

9 A. I don't recall if February '16 was
10 when these conditions were put in place or if
11 there were other conditions put in place and
12 then these were added and that's why it says
13 February 2016. So I'm not sure about that.

14 Q. Okay. Well, we may see more
15 documents that will refresh your recollection.

16 A. Okay.

17 Q. On page 15 there's additional
18 things listed. A patient is from outside the
19 usual pharmacy geographic area. What, in your
20 experience, does it mean to be inside or
21 outside the usual pharmacy geographic area?

22 A. Well, that's very subjective. I
23 would say in Lake County, someone coming from
24 the Youngstown area or coming from the Akron
25 area would be outside the geographic area.

1 That being said, somebody could
2 think that Cleveland was outside of the
3 geographic area. It's a very subjective --
4 subjective statement. Depending on what part
5 of the state you're in, I guess, geographic
6 area could be a much larger or much smaller
7 area.

8 Q. So as a subjective matter, was
9 this left up to the professional judgment of
10 the pharmacist?

11 A. Yes.

12 Q. Do you recall if the Ohio Board of
13 Pharmacy ever came out and said, you know, we
14 deem X miles to be outside the normal
15 geographic area, or the usual geographic area?
16 Did they ever do that?

17 A. I don't recall the Board ever
18 doing that.

19 Q. Okay. Another reason why a
20 pharmacist as of February of '16, according to
21 this document, would query OARRS would be if he
22 had reason to believe a patient had received
23 prescriptions for controlled substances from
24 more than one prescriber in the preceding three
25 months unless the prescribers were at the same

1 location.

2 Do you see that?

3 A. Yes.

4 Q. And is that one of the reasons
5 that you know as an agent, the pharmacist is
6 supposed to check OARRS?

7 A. Yes.

8 Q. Okay. Or -- and, lastly, a
9 patient is exhibiting signs of potential abuse
10 or diversion, and then it gives a list:
11 overutilization, early refills, appears overly
12 sedated or intoxicated upon presenting a
13 prescription, unfamiliar patient requesting a
14 drug by specific name.

15 Again, is that one of the factors
16 that you know as an agent pharmacists should check
17 OARRS?

18 A. Yes.

19 Q. Are some of these things
20 subjective and up to the pharmacist? I'm
21 looking at things, for example, appears overly
22 sedated. Is that --

23 A. Yes.

24 Q. How do you exactly do that?

25 That's a --

1 A. Right, that's subjective.

2 Q. That's subjective. Okay.

3 Now, when a pharmacist checks
4 OARRS -- and break down the time period if you
5 need to -- can a pharmacist go in and check the
6 prescription history for a doctor, for example;
7 Dr. Smith sends in a patient, the pharmacist
8 has reason for suspicion, can the pharmacist go
9 in and say, I want to see everything
10 Dr. Smith's been up to in the last year?

11 A. I don't believe they have that
12 ability.

13 Q. Okay. Is there a reason why OARRS
14 doesn't allow pharmacists to check on the
15 history -- the prescription history for
16 prescribers, or is that just something that
17 exists as a limitation in the database?

18 A. Well, yeah, OARRS is -- you know,
19 it's written in -- it's codified, so I don't
20 know if that's something that's written in the
21 code or -- I don't know. That's --

22 Q. Okay.

23 A. I don't make the OARRS access
24 decisions.

25 Q. Okay. Has that always been the

1 case, that -- as far as you know, that
2 pharmacists couldn't check on prescribers'
3 prescription history in OARRS?

4 A. As far as I know.

5 Q. Okay. What about prescribers,
6 can -- on pages 16 and 17 of this Exhibit 2,
7 there's an indication that prescribers must
8 also query OARRS under certain circumstances.

9 Do you see that?

10 A. Yes.

11 Q. Some of those circumstances
12 include before initially prescribing or
13 personally furnishing an opioid analgesic or a
14 benzodiazepine to a patient, they must request
15 patient information from OARRS for at least the
16 last 12 months?

17 A. Correct.

18 Q. Do you see that?

19 A. Yes.

20 Q. And so these are at the point of
21 actually prescribing, the doctor is supposed to
22 go into OARRS under these circumstances and
23 check the prescription history?

24 A. Correct.

25 Q. Okay. Is that a diversionary

1 tool? Is that the reason why it's in OARRS so
2 that doctors, before they write the
3 prescription, they check OARRS and have, you
4 know, at least OARRS' body of knowledge for the
5 patient's history?

6 A. It's not only diversionary, it's
7 to protect the patient, it's to keep the
8 patient safe.

9 Q. Okay. And then prescribers should
10 check OARRS, including a border state's
11 information, when they're in a county bordering
12 another state?

13 Trumbull County borders
14 Pennsylvania; is that correct?

15 A. Yes.

16 Q. But Lake County does not?

17 A. Correct.

18 Q. So according to OARRS, doctors in
19 Trumbull County should check the Pennsylvania
20 PDM program; is that right?

21 A. According to this, yes.

22 Q. Does the OARRS system integrate
23 with the Pennsylvania PDM system or any other
24 state systems?

25 A. You know, I'm not sure about the

1 inner workings of OARRS. I know there's been
2 talk of a national integration, but I don't
3 know where that stands.

4 Q. And you don't know if they -- any
5 border states that connect to OARRS?

6 A. Not to my knowledge.

7 Q. Okay.

8 A. I know we've changed -- APRS
9 (phonetic) now administers -- we went from an
10 in-house administration of OARRS to a
11 third-party administration who also administers
12 other states, but I don't know who's connected
13 or who's, you know, interlocked or what.

14 Q. All right. Then just to finish,
15 when the doctor or prescriber must query OARRS,
16 they should also query OARRS if they're
17 treating with an opioid or a benzodiazepine for
18 more than 90 days. That's another reason why
19 they should check OARRS before issuing the
20 prescription?

21 A. Correct.

22 Q. And then to check OARRS at least
23 90-day intervals thereafter, correct?

24 A. Correct, yes.

25 Q. And then other reasons include

1 that the patient was selling prescription
2 drugs, forging or altering prescriptions,
3 stealing or borrowing drugs, overdose, things
4 of that nature. Is that information that's in
5 OARRS when a prescriber accesses OARRS before
6 writing a prescription? Will he see things
7 like that if somebody has been convicted for
8 selling drugs --

9 A. No.

10 Q. -- or altering prescriptions?

11 A. No.

12 Q. Okay. How's the doctor going to
13 know that, through news reports or --

14 A. Sure. Through news reports or,
15 you know, other sources, family members, you
16 know, acquaintances who may report that and,
17 you know, maybe they'll check the court
18 website.

19 Q. Okay. But I just wanted to know
20 if it was in OARRS or not.

21 A. No.

22 Q. Take a look at Exhibit 3, please,
23 Edwards Exhibit 3. Have you ever seen this
24 document? It's called HB 49 Testimony
25 Steven W. Schierholt, Executive Director.

1 A. I don't recall seeing it until I
2 saw it in this book of exhibits.

3 Q. Do you recognize that name,
4 Mr. Schierholt, as the executive director of
5 OARRS?

6 A. Yes.

7 Q. The reason I included this exhibit
8 was looking for information about the size of
9 the Board and things of that nature. And this
10 exhibit is approximately as of 2018. It says
11 that the Board had 68 employees. Is that about
12 right, in your recollection, or would you have
13 no reason to know?

14 A. In my recollection at that time,
15 that sounds about right.

16 Q. How many of those are agents or
17 specialists?

18 A. I don't know an exact number.

19 Q. Can you ballpark it? Is it a
20 dozen, couple dozen?

21 A. I would say -- well, when I got
22 hired, I think there were like about 15 or 20,
23 and I think -- I think we've more than doubled,
24 so I would say -- I would say more than a
25 couple dozen.

1 Q. Okay. And is it the agents and
2 specialists that do the pharmacy inspections?
3 In other words, I'm not missing another
4 category of like inspector?

5 A. Well, at this time in 2016, I
6 don't believe we had inspectors yet, but
7 currently we have a class of employee that is
8 called inspector.

9 Q. And when were the inspector
10 employees added?

11 A. It may have been around -- I don't
12 know -- five years -- four or five years ago.

13 Q. Okay. And why were inspectors
14 added on top of agents and specialists?

15 A. I believe due to the -- just the
16 caseload and responsibilities of the agents.
17 Inspectors were added to alleviate some of
18 that -- some of that work.

19 Q. How many inspectors are there now
20 with the Board?

21 A. I believe there are -- I think
22 we're authorized to have two per area of the
23 state, so a total of eight. But I don't know
24 that we currently have eight employed. I think
25 there's a couple -- one or two vacancies.

1 Q. You said there are areas. Does
2 the Board break down the state between
3 northeast, northwest?

4 A. Yes.

5 (Reporter interrupted.)

6 THE WITNESS: Sorry, Patti.

7 A. It's the northeast, northwest,
8 southeast, and southwest are the four
9 quadrants.

10 BY MR. BARNES:

11 Q. Okay. And you've always been
12 assigned to the northeast quadrant, correct?

13 A. Correct. That being said, our
14 agents are told we are employees of the State.
15 We may be assigned to a certain area of the
16 state, but that doesn't mean we can't get
17 assigned to a case in another area.

18 Q. Okay. Still focusing on
19 Exhibit 3, there's a reference on page 1 to the
20 Board's duties are to enforce the drug laws.
21 We've seen this before, but what's added here
22 is the medical marijuana control program. I
23 guess that's newer law that you guys enforce?

24 A. Yes.

25 Q. And right below that there's a

1 reference to the Board regulating more than
2 45,000 pharmacists, pharmacy interns, and sites
3 where dangerous drugs are purchased and stored.
4 Does that include pharmacies and warehouse
5 distribution centers?

6 A. Yes.

7 Q. Have you yourself ever inspected a
8 warehouse distribution center?

9 A. I believe I have inspected one or
10 two warehouses, entities licensed as a
11 warehouse, but not -- I don't believe I was
12 ever in a warehouse that stored drugs. I
13 believe they were licensed as a warehouse, but
14 they had mainly devices and other products like
15 that. I may have -- I don't recall.

16 Q. Okay. Is most of your experience
17 in terms of inspections the inspection of
18 pharmacies?

19 A. Yes.

20 Q. Okay. This paragraph also
21 references that these site licenses include
22 retail pharmacies, wholesalers, hospitals,
23 prescriber offices, veterinary clinics, nursing
24 homes, prisons and jails, emergency medical
25 service organizations, medical gas distributors

1 and pain management clinics.

2 Are these sites where controlled
3 substances are stored and dispersed or
4 distributed?

5 A. Some of them.

6 Q. Okay. For example, prescriber
7 offices, some prescriber offices have licenses
8 to dispense controlled substances?

9 A. Correct.

10 Q. And hospitals certainly, I would
11 expect, would have licenses to do the same?

12 A. Yes.

13 Q. Okay. Nursing homes and prisons,
14 I guess they would have some type of license to
15 dispense?

16 A. Correct.

17 Q. Okay. There's a reference here to
18 the Board, beginning in 2018, licensing 42,000
19 pharmacy technicians, as well as prescriber
20 offices that provide treatment of opioid
21 addiction using buprenorphine. That's why I
22 didn't become a doctor. I can't say these
23 words.

24 So you began regulating techs --
25 pharmacy techs in 2018. Was there an

1 initiative that you recall to get these techs
2 under license?

3 A. I don't recall a specific
4 initiative, but it was put into code and we did
5 license -- or register them.

6 Q. Page 2, there's a nice history
7 here of the duties of the Board right at the
8 top. The Board of Pharmacy is charged with
9 preventing, detecting, and investigating the
10 diversion of dangerous drugs, including
11 controlled substances. The Board investigates
12 and presents evidence of violations of federal,
13 state drug laws by any person and refers them
14 for criminal prosecution and/or administrative
15 action.

16 Does that seem accurate to you?

17 A. Yes.

18 Q. Are there any other entities or
19 agencies that you can think of that have these
20 similar duties in Ohio?

21 A. Similar, but not exact. I would
22 say the other -- the other regulatory boards
23 that I've worked with, the medical board, the
24 dental board, the nursing board, Bureau of
25 Workers' Compensation, there are other agencies

1 and boards who investigate these type of
2 things. That's primarily our responsibility,
3 but sometimes other agencies get involved as
4 well.

5 Q. I see. Now, does the Board have
6 full law enforcement powers and other powers
7 such as the right to issue subpoenas, the right
8 to refer for criminal prosecution, things of
9 that nature?

10 A. We have those two authorities that
11 you mentioned, but I wouldn't say we have full
12 law enforcement authority. We don't have
13 arrest powers.

14 Q. Okay.

15 A. So I would consider that full law
16 enforcement authority.

17 Q. I see. There's a reference here
18 that the Board investigates physicians, nurses,
19 dentists, and other individuals that may not be
20 licensed by the agency. So you actually do --
21 the Board actually does investigate these
22 individuals, physicians, nurses, and dentists?

23 A. We do because there are instances
24 where they are employed by one of our licensed
25 sites.

1 Q. I see.

2 A. So they're an employee of an
3 office, a doctor's office or, you know, other
4 entity that's licensed by us, we would
5 investigate that.

6 Q. Down below, just to hopefully wrap
7 up our -- a little bit of our OARRS overview,
8 there's a reference to OARRS being established
9 in 2006. It collects information on all
10 prescriptions for controlled substances that
11 are dispensed by pharmacies and personally
12 furnished by licensed prescribers in Ohio.
13 Drug wholesalers are also required to submit
14 information on all controlled substances sold
15 in the state. The data is reported every 24
16 hours and is maintained in a secure database.

17 Is that an accurate description of
18 how OARRS functions?

19 A. I'm not familiar with how OARRS
20 stores or requires or maintains the data.

21 Q. I see. But do you know that OARRS
22 does collect all prescription data, not only
23 from pharmacies, but also from prescribers?

24 A. Yes.

25 Q. And it also collects information

1 from drug wholesalers?

2 A. Yes.

3 Q. So the Board has a comprehensive
4 view of all pharmaceuticals, including
5 controlled substances, coming into the state
6 being distributed by wholesalers and being
7 dispensed by pharmacies?

8 A. Currently. I don't know how -- I
9 know that throughout the history of OARRS there
10 were new requirements that were placed on folks
11 like wholesalers and doctors and pharmacies,
12 but I don't recall -- I don't believe at the
13 start of OARRS we had access to all this
14 information.

15 Q. I see. But -- all right. So over
16 time OARRS developed and evolved and ultimately
17 was able to get all this information into the
18 database?

19 A. Correct.

20 Q. Okay. Down below it says, OARRS
21 serves multiple functions, including a patient
22 care tool.

23 How is it a patient care tool?

24 A. I believe that means it enables a
25 doctor to do more -- get a bigger picture of

1 the patient's history and the drugs that they
2 may have been taking. So it enables them to
3 better care for the patient.

4 Q. Okay. It further references drug
5 epidemic early warning system. How does it
6 fulfill that function?

7 A. I can only speculate, but I think
8 what that means is that it notifies people of
9 trends or something that's happening that maybe
10 some action may need to be taken on.

11 Q. Okay. And then it says it's a
12 drug diversion and insurance fraud
13 investigative tool. Is that how you view
14 OARRS, one of its functions, is to assist in
15 drug diversion and fraud investigation?

16 A. It -- primarily drug diversion,
17 but also, yes, it tracks how medications are
18 paid for so we can assist with fraud
19 investigations as well.

20 Q. Okay. On page 3 of this exhibit,
21 down below at the bottom where it says,
22 Currently Board agents and specialists are
23 charged with conducting inspections as well as
24 investigations of individuals and entities in
25 violation of Ohio laws and rules, is that -- is

1 that accurate?

2 A. Yes.

3 MR. BARNES: I'm sorry. Clint,
4 we're in Exhibit 3, page 4.

5 THE WITNESS: Page 3, I believe.

6 MR. BARNES: Yeah. Page 3.
7 Sorry.

8 BY MR. BARNES:

9 Q. Then on page 4 in the first
10 paragraph it says, Routine inspections allow
11 Board staff to review facilities to ensure they
12 comply with security, recordkeeping, and other
13 rules designed to deter and detect the
14 diversion of prescription drugs including
15 opioids.

16 Is that an accurate description,
17 Mr. Edwards, of the purpose of routine
18 inspections conducted by the Board of Pharmacy?

19 A. Yeah, along with the -- yeah. I
20 mean, that's one of our functions, one of the
21 reasons we complete inspections.

22 Q. Okay. The paragraph immediately
23 below that references an increase in the number
24 of high-risk licensees due to the passage of SB
25 319. These entities include 1,035 prescriber

1 offices that purchased more than 3 million
2 doses of opioids in 2015 and clinics that
3 provide addiction treatment using controlled
4 substances.

5 What is your understanding of a
6 high-risk licensee?

7 A. I don't know. That's never been
8 explained to me.

9 Q. You never heard that term as an
10 agent?

11 A. No.

12 Q. Is it true that prescriber
13 offices, in your experience, purchase a lot of
14 dosages of opioids on a year-to-year basis?

15 A. No.

16 MR. CIACCIO: Objection to form.
17 Sorry. This is Joe Ciaccio. Objection to form.
18 BY MR. BARNES:

19 Q. Go ahead, Mr. Edwards.

20 A. No. That's not my experience.

21 Q. Not your -- what is your
22 experience?

23 A. Well, primarily the medications
24 are being purchased by pharmacies, not
25 prescribers. I -- very few prescribers store

1 controlled substances in their facilities.

2 Now, maybe -- this paragraph may
3 be referring to medication-assisted treatment
4 or, you know, opioid abuse clinics such as
5 Suboxone clinics. If that's what it's
6 referring to, then they would be ordering more
7 medications than, say, your standard
8 prescribers. But my experience has been that
9 prescribers don't always order controlled --
10 don't commonly order controlled substances or
11 store controlled substances in their offices.

12 Q. Okay. And you've never heard the
13 term high-risk licensee before seeing it here?

14 A. No.

15 Q. Okay. Down below there's a
16 reference to criminal cases investigated by the
17 Board. They're often time consuming and
18 complex. They involve undercover visits,
19 search warrants, interviews, experts,
20 prosecutor consultations, criminal
21 adjudication, et cetera.

22 Is that your experience as an
23 agent, that these criminal cases are often
24 complex and take a long time to prosecute?

25 A. Yes, occasionally.

1 Q. Down at the end of this paragraph
2 there's a reference to stopping those engaged
3 in criminal behavior who are contributing to
4 Ohio's drug overdose epidemic.

5 Is that -- does that comport with
6 your experience as an agent, that criminal
7 behavior is contributing -- or has been and is
8 contributing to the opioid overdose epidemic?

9 A. Well, certainly any time that
10 medication is taken out of legitimate channels
11 and diverted, that would be criminal behavior.
12 So in that sense, yes, diversion is
13 contributing to the epidemic.

14 Q. And then the next page at the
15 bottom there's a reference to expanding access
16 to OARRS. It's a reference to physician and
17 pharmacist access to OARRS has helped to curb
18 the number of opioids prescribed by providing
19 critical information about a patient's
20 prescription history.

21 Has that been your experience as
22 an agent, that as OARRS access was expanded
23 that the number of opioid prescriptions has
24 gone down?

25 A. Yes.

1 Q. How significant of a trend is
2 that?

3 A. I don't know the specific numbers,
4 but it's -- I feel like it's fairly
5 significant. I've seen charts and graphs on it
6 in the past, but I don't know the exact
7 numbers.

8 Q. Okay. At the end of that
9 paragraph there's a reference to the record
10 retention for OARRS will be extended from three
11 to five years to provide more information on
12 prescribing history.

13 Is that what you recall that the
14 record retention time period is for OARRS now?

15 A. I know now that it's five years,
16 yes. I don't know when it became five years.

17 Q. Now, Exhibit 4 we referenced
18 earlier. This is your August 26, 2014 training
19 guide, A Guide for Law Enforcement.

20 Do you see that?

21 A. Yes.

22 Q. Is this the approximate one-year
23 or more or less time period in which the Board
24 was sending out experienced agents like
25 yourself to train law enforcement people on how

1 to use OARRS?

2 A. I believe so.

3 Q. Is this something that you
4 prepared personally, or did somebody prepare it
5 for you and you reviewed it and approved it?

6 A. I worked on it with Jesse
7 Wimberly, who's one of our supervisors. He and
8 I were tasked with conducting these trainings.

9 Q. Okay. So this is as of August 26
10 of '14. If you would go to the Bates stamped
11 page ending in 26994.

12 A. 994?

13 Q. Yes. Actually. I misspoke. 966.
14 Sorry about that.

15 A. I'm excited you're skipping all
16 those.

17 Q. Yeah. Yeah.

18 A. Okay.

19 Q. Yeah. There's a description here
20 in this training manual describing the
21 reporting requirements for OARRS. All
22 pharmacies, prescribers who personally furnish
23 medication and wholesalers must submit
24 controlled substance dispensing data to OARRS.
25 And pharmacies and prescribers must report at

1 least daily; wholesalers must report monthly.

2 Does that refresh your
3 recollection that as of this -- as of 2014,
4 that was the status of the requirements for
5 submitting to OARRS?

6 A. Yes.

7 Q. A couple pages after that, there's
8 a reference to information sharing. OARRS may
9 provide patient dispensing data to prescribers,
10 pharmacists, law enforcement, individuals,
11 their own Rx history, and certain regulatory
12 agencies.

13 Is that how you understood OARRS
14 to work in 2014?

15 A. Yes.

16 Q. Overall, Mr. Edwards, is there any
17 other agency or entity in Ohio that has the
18 comprehensive information that OARRS has in
19 terms of controlled substances, i.e., every
20 prescription dispensed by pharmacists, all
21 drugs distributed by wholesalers?

22 A. You mean data separate from OARRS?

23 Q. Yeah. I mean, is there a
24 competing -- does anybody else have a competing
25 or better database than OARRS does concerning

1 the flow of controlled substances in Ohio?

2 A. Not accessible to folks like me
3 or law enforcement that I'm aware of. I
4 believe -- well, I don't know if this is still
5 the case, but I can recall there being some
6 sort of database that drug sales folks had
7 access to and that's how they used to decide
8 which doctors they would call on, but that was
9 not anything that I ever had access to.

10 Q. Okay. We've covered when doctors
11 and pharmacists must access OARRS. Do you
12 remember that testimony a few minutes ago?

13 A. Yes.

14 Q. To your knowledge, has the Board
15 ever required pharmacists to access any other
16 database besides OARRS before filling a
17 prescription?

18 A. I mean, their own database, their
19 own -- you know, part of the drug utilization
20 review is to review their own database and
21 prescription history. Because OARRS obviously
22 is just controlled substances and gabapentin.
23 So their -- prior to issuing a prescription,
24 they should be reviewing their own history.

25 Q. I see. Okay. Understood. Does

1 the year 2011 ring a bell to you as to when
2 OARRS became mandatory as opposed to
3 discretionary?

4 A. Possibly. I don't -- I remember
5 2011 was when we started licensing pain
6 management clinics, but I don't recall if that
7 was the year for OARRS as well.

8 Q. Were pain management clinics a
9 source of a lot of opioid prescriptions?

10 A. Yes.

11 Q. How significant --

12 MR. CIACCIO: This is Joe Ciaccio.

13 I'm sorry. Can I just get an objection to form to
14 the last question? Thanks.

15 BY MR. BARNES:

16 Q. How significant of a source were
17 the pain management clinics for opioid
18 prescriptions?

19 A. I would say that they were the
20 primary source.

21 Q. Okay. And what is a pain
22 management clinic in your experience as an
23 agent?

24 A. Currently, it's a licensed clinic
25 that provides pain management to their

1 patients -- to over 50 percent of their
2 patients. So if they're prescribing opiates
3 for pain management to over 50 percent of their
4 patients, they're required to be licensed by
5 the Board of Pharmacy as a pain management
6 clinic.

7 Q. That's since about 2011, you said?

8 A. Yes.

9 Q. Do these opioids, in your
10 experience, do they have legitimate medical
11 usages, including, for example, pain management
12 for patients in pain?

13 A. Yes.

14 Q. Now, what -- in your experience,
15 what do pharmacists have access to? And I know
16 this changed over time, but I'm trying to get
17 an understanding of when a pharmacist accesses
18 OARRS, they do that on a patient basis,
19 correct, on a specific patient basis?

20 A. Correct.

21 Q. And they get a patient history of
22 prescription or controlled substances for that
23 patient --

24 A. Correct.

25 Q. -- over I guess three to five

1 years?

2 A. It's -- I believe the default is
3 one year, but they can go back longer than
4 that.

5 Q. I see.

6 A. Two years. I'm sorry.

7 Q. Can a pharmacist say, I want to
8 take a look at, you know, what another pharmacy
9 is doing, the history of dispensing of the
10 pharmacy down the street? Is that accessible
11 by the pharmacist?

12 A. Not through OARRS. They can call
13 the pharmacy down the street and ask them about
14 a patient.

15 Q. Okay. But they can't -- they
16 can't take a look at what other pharmacists or
17 pharmacies are doing in terms of dispensing
18 controlled substances?

19 A. Not unless it's related to a
20 specific patient.

21 Q. I see. Okay. So the entree for
22 pharmacists is this patient, go in and get the
23 information for this patient?

24 A. Correct. Give them pharmacy
25 information on that patient. Like, for

1 instance, tell them that that patient had gone
2 to another pharmacy, but it would not give them
3 any additional information on that pharmacy.

4 Q. Okay. Do pharmacies have the
5 subpoena or other law enforcement powers that
6 the Board has?

7 A. Not to my knowledge.

8 Q. Do pharmacies, other than
9 accessing OARRS under the conditions we
10 covered, have the duties that the Board has to
11 analyze the OARRS data for investigative leads?

12 A. No.

13 Q. Have you ever heard of the doctor
14 shopper reports or the 640 reports issued by
15 the Board based upon the OARRS data?

16 A. Yes.

17 Q. And what is the doctor shopper
18 report and what is the 640 report?

19 A. The 640 report is a list of
20 prescribers who have, I believe, 640 unique
21 patients in a month. And then the doctor
22 shopper report is a list of patients who have
23 seen five prescribers and been to five
24 pharmacies within three months.

25 Q. Is this something that the Board

1 can pull out of the OARRS data for
2 investigative leads?

3 A. Yes.

4 Q. Are these doctor shopper reports
5 or 640 reports shared with the pharmacies?

6 A. No.

7 Q. Does OARRS evaluate patient data
8 and set up red flags within the OARRS system so
9 that pharmacists can see that OARRS considers
10 this patient a potential problem?

11 A. Like you mean like a blinking
12 light or a flashing something that tells you
13 it's a red flag? No.

14 Q. Can -- does OARRS actually
15 evaluate any of the data and say, you know,
16 based on this data, you shouldn't fill this
17 prescription?

18 A. No. That's a professional
19 judgment call made by the pharmacist after
20 reviewing OARRS.

21 Q. I see. So OARRS provides
22 information. It doesn't tell you what to do?

23 A. Correct. And OARRS is -- it's
24 just a guide. So that information has to be
25 verified.

1 Q. OARRS can identify top
2 prescribers, though; is that correct?

3 A. It's -- the information in OARRS
4 can be used by our agency and those in the
5 OARRS department to -- yes, to identify top
6 prescribers based on number of prescriptions
7 and volume of medication being prescribed.

8 Q. As well as patients and their
9 activities, et cetera?

10 A. Patients and the prescriptions
11 filled, yes.

12 Q. Can it identify top areas where
13 opioids are being dispensed and the types of
14 drugs that are being dispensed?

15 A. You mean like by ZIP Code?

16 Q. Yeah, any other factor like that.

17 A. Yeah, I believe so.

18 Q. Do you know anything about the
19 statistical models used by the Board of
20 Pharmacy on the OARRS data? And I'll -- do you
21 know Chad Garner?

22 A. I do know Chad Garner. Yeah, and
23 he is the one who comes up with the algorithms
24 or, as you said, statistical models, I think
25 you said. I don't know what goes into those

1 models.

2 Q. Okay. I was hoping you did
3 because he testified to between 100 and 500
4 statistical models that OARRS uses for tips for
5 investigators. But you don't know what those
6 algorithms are or --

7 A. No.

8 Q. -- how he figures them out; is
9 that right?

10 A. That's correct. I do not.

11 Q. Okay. Now, you mentioned earlier
12 that you got training on the Ohio Revised Code,
13 Administrative Code, and the CFR?

14 A. Correct.

15 Q. And are you familiar with the
16 so-called security requirement of the Ohio
17 Administrative Code that pharmacies need to
18 meet?

19 A. I mean, I can't recite it to you,
20 but I'm aware it exists.

21 Q. Is that the primary requirement
22 that pharmacies need to meet as far as the
23 Board is concerned in terms of having effective
24 controls against theft and diversion of
25 dangerous drugs?

1 A. I believe so.

2 Q. And I don't want to make this a
3 memory game, so let's look at this Exhibit 5.
4 Do you recognize this as the Ohio
5 Administrative Code security requirement?

6 A. Yes.

7 Q. And is that the main requirement
8 that you know as an agent pharmacies needed to
9 meet at all times?

10 A. Yes.

11 Q. Is one of the purposes of your
12 inspections of pharmacies, excuse me, to make
13 sure the pharmacies were adhering to this, I'll
14 call it OAC, Ohio Administrative Code, this OAC
15 requirement?

16 A. Yes.

17 Q. It says -- this is OAC 4729-9-05.
18 You have to have effective and approved
19 controls and procedures to deter and detect
20 theft and diversion of dangerous drugs.

21 I just want to stop there for a
22 moment. What does it mean to have effective
23 controls, in your experience?

24 A. Policies in place to ensure
25 effective security control.

1 Q. Now, did that --

2 MR. APPEL: This is Henry Appel.

3 Can we take a short break?

4 MR. BARNES: Yeah. Let me just
5 finish up this line of questioning on this
6 paragraph and then that will be a nice breaking
7 point. Is that okay?

8 MR. APPEL: Okay. That would be
9 fine.

10 MR. BARNES: All right. Thank you.

11 BY MR. BARNES:

12 Q. Having policies and procedures,
13 was that on a case-by-case basis? In other
14 words, it depended on the facts and
15 circumstances of each location, it wasn't a
16 one-size-fits-all, you better have this policy
17 or else you're not in compliance?

18 A. Well, I mean, everybody is
19 expected to follow this. The manner in which
20 they follow it would vary, I suppose, depending
21 on the type of building they're in, the type of
22 employees, and those type of things.

23 Q. Okay. And then it says, effective
24 and approved controls. What are approved
25 controls?

1 A. Well, prior to being licensed,
2 there are inspections conducted of terminal
3 distributors prior to issuing a license.

4 Q. I see. And you have to be
5 approved based upon an inspection review of
6 your controls and procedures?

7 A. Well, the security of the
8 building. I'm not saying -- you don't have to
9 be approved by an inspection of the procedures
10 in place to, you know -- for all this stuff,
11 like ordering and, you know, drugs and stuff,
12 but the physical security of the facility is
13 inspected prior to issuing license.

14 Q. I see. Okay. So you have to
15 undergo an inspection even before you can open
16 up?

17 A. Correct.

18 Q. I see. Has the Board ever
19 provided specific guidance about what effective
20 controls are, to your knowledge?

21 A. Not to my knowledge. I mean, I
22 don't recall that.

23 Q. Do you know if this Ohio security
24 requirement tracks the federal requirement in
25 the CFR?

1 A. I don't -- I'm not sure about
2 that.

3 Q. Does the Board evaluate compliance
4 with the security requirement using multiple
5 factors in order to determine whether
6 substantial compliance has been met?

7 A. What do you mean by that?

8 Q. Well, I'm specifically referring
9 to this same security requirement code section
10 (B), substantial compliance with the standards
11 set forth in Rule 4729-9-11 of the
12 Administrative Code may be deemed sufficient by
13 the State Board of Pharmacy after evaluation of
14 the overall security system and needs of the
15 applicant, licensee, or registrant. In
16 evaluating the overall security system of a
17 licensee, registrant, or applicant, the State
18 Board of Pharmacy may consider any of the
19 following factors as deemed relevant for
20 compliance with security requirements. And
21 then there's a list of 14 factors.

22 Do you see that?

23 A. Yes.

24 Q. Is that your understanding as an
25 agent, that in terms of determining substantial

1 compliance with the security requirement, the
2 Board will consider any number of 14 factors,
3 including the type of activity conducted, type
4 and form of dangerous drugs handled, quantity
5 of dangerous drugs handled, location of the
6 premises, type of building construction,
7 vaults, safes, adequacy of key control systems,
8 adequacy of electronic detection and alarm
9 systems, extent of unsupervised public access,
10 adequacy of supervision over authorized
11 employees having access to any areas containing
12 dangerous drugs --

13 A. Yes.

14 Q. -- et cetera, procedures for
15 handling business guests and visitors,
16 availability of local police, and then,
17 finally, adequacy of the licensee's,
18 registrant's, or applicant's system for
19 monitoring the receipt, manufacture,
20 distribution, and disposition of dangerous
21 drugs and its operations.

22 Does that refresh your
23 recollection that these are the factors the
24 Board takes into account for each individual
25 pharmacy when determining substantial

1 compliance with the security requirement?

2 A. This is the general list of
3 factors that are taken into account when we go
4 in and license. I believe this is saying you
5 have to provide all this in order to be
6 licensed. So this is -- this stuff is
7 evaluated prior to issuing a license.

8 Q. And it's not about what --

9 MR. APPEL: Bob, you said you were
10 going to wait to the end of the paragraph. You
11 moved from (A) to (B). Do you want to take a
12 break at this moment?

13 MR. BARNES: I did say that, Henry,
14 and I'm sorry. Just give me one minute. I just
15 want to wrap up 9-05.

16 MR. APPEL: Well, I mean, that rule
17 goes on for another two pages and you've been
18 reading it. If I could just -- I'd like to talk
19 to my client for a minute before you go on, if
20 that's not a problem.

21 MR. BARNES: All right. Why don't we
22 take a ten-minute break then?

23 MR. APPEL: Thank you.

24 THE VIDEOGRAPHER: Off the record
25 10:38.

1 (Off the record.)

2 THE VIDEOGRAPHER: We're on the
3 record at 10:49.

4 BY MR. BARNES:

5 Q. All right. Mr. Edwards, we're
6 back after a short break. We were in the
7 middle of talking about the Ohio security
8 requirement in OAC 4729-9-05, and I had
9 actually read through a list of the substantial
10 compliance factors in 05 subsection (B).

11 Do you see that?

12 A. Yes.

13 Q. And you were explaining to me that
14 at the time to get your license, you had to
15 show the Ohio Board of Pharmacy in order to get
16 your license that you complied with the
17 security requirement; is that correct?

18 A. Correct.

19 Q. And this regulation allows for
20 substantial compliance based upon multiple
21 factors, correct?

22 A. Correct.

23 Q. A lot of these factors appear to
24 be physical, you know, in terms of location of
25 the premises and keys and vaults and alarm

1 systems and things of that nature. Do you
2 agree with that?

3 A. Yes.

4 Q. But some of them are, I would say,
5 evaluative factors like the type of activity
6 conducted. How do you understand that term?
7 What type of activity? If you're dealing with
8 so-called dangerous drugs --

9 A. Well, that's --

10 Q. -- are there levels of dangerous
11 drugs?

12 A. I would say type of activity would
13 mean, are you -- is it a doctor's office, is it
14 a pharmacy, is it -- you know, what type of --
15 is it a veterinary clinic; like the type of
16 activity would mean what they are doing at that
17 particular site.

18 Q. I see. I see. It says, type and
19 form of dangerous drugs handled is the -- I
20 guess there are schedules for dangerous drugs,
21 Schedules I through V, is that what that refers
22 to?

23 A. Dangerous drugs are nonscheduled
24 drugs. Those would be legend drugs. So
25 scheduled drugs are controlled substances

1 I through V. And then dangerous drugs are any
2 other --

3 Q. Oh, okay.

4 A. -- drug that requires a
5 prescription. So the type and form -- so
6 dangerous drugs would cover all prescription
7 drugs including controlled substances.

8 Q. Oh, okay. All right. Yeah, I was
9 struggling there for a minute. I was trying to
10 remember the definition that I thought
11 dangerous drugs -- so dangerous drugs includes
12 controlled substances?

13 A. Correct.

14 Q. And so if a facility or an entity
15 was only distributing, say, Schedule III, IV, V
16 controlled drugs and no controlled II drugs,
17 would that be a factor taken into account by
18 the Board --

19 A. Sure.

20 THE REPORTER: I didn't hear that
21 last part. You trailed off.

22 THE WITNESS: Me or Mr. Barnes?

23 THE REPORTER: Mr. Barnes.

24 THE WITNESS: I said sure.

25 THE REPORTER: I know.

1 Mr. Barnes.

2 MR. BARNES: Oh, you didn't hear
3 that? I'm sorry. I'll repeat the question.

4 THE REPORTER: You just trailed
5 off at the end. That's all.

6 MR. BARNES: Yeah. I was looking
7 down. Sorry.

8 BY MR. BARNES:

9 Q. The question is, the type and form
10 of dangerous drugs handled, and specifically if
11 you're only handling certain lower level of
12 controlled substances, is that a factor that
13 the Board takes into account?

14 A. Yes. Or if it's -- if they maybe
15 are not even handling any controlled
16 substances. It may just be, you know, a
17 specific type of drug that's being handled at
18 that location that's not a controlled
19 substance.

20 Q. Okay. And what about an entity
21 that's only distributing to itself as opposed
22 to distributing to third parties, is that a
23 factor that the Board takes into account?

24 A. Like what type of entity are you
25 talking about?

1 Q. Well, say a pharmacy that has a
2 warehouse that has controlled substances and
3 only distributes to its own affiliated
4 pharmacies.

5 A. Sure, that would be taken into
6 account.

7 Q. Okay. Now, you mentioned that
8 this is something that a pharmacy has to meet
9 at the time of license, but do they have to
10 continue to meet these requirements at renewals
11 of the license? I mean, it's not a one-time
12 thing, I met it and I can forget it?

13 A. Correct.

14 Q. So when the Board renews a
15 license, does it evaluate these factors again
16 and say, has anything changed, are you doing
17 what we thought you were doing, have there been
18 significant changes in your operations, things
19 of that nature?

20 A. I don't know exactly what the
21 renewal forms state.

22 Q. These other factors that are taken
23 into account under the regulation, one of the
24 factors, number 14, adequacy of the licensee's,
25 registrant's, or applicant's system for

1 monitoring the receipt, manufacture,
2 distribution, and disposition of dangerous
3 drugs in its operations, is that a reference to
4 the internal controls and other systems that
5 the licensee has to handle these drugs and to
6 take them in and store them and dispense them?

7 A. I believe so.

8 Q. Okay. I just want to make sure
9 I'm reading it the same way you are. You have
10 more experience in this area than I do. Do you
11 read it in any other way?

12 A. No.

13 Q. Now, this regulation references
14 specifically -- it says, The Board of Pharmacy
15 shall use the security requirements set forth
16 in Rule 4729-9-11. And right behind these
17 pages should have been -- yeah, there it is.
18 The third page of this exhibit is 4729-9-11.
19 Have you seen this regulation, and are you
20 familiar with it?

21 A. Yes.

22 Q. And so the security regulation
23 refers to this other regulation. And this
24 regulation, if you read -- if you look at
25 subsection (A), it's for a pharmacy. There are

1 various provisions under there, but the first
2 one talks about pharmacist personal
3 supervision. Is that something that you're
4 familiar with, that the Board takes into
5 account and requires pharmacists to personally
6 supervise the operations at a pharmacy?

7 A. Yes.

8 Q. And when the pharmacist can't
9 provide such personal supervision, there has to
10 be a certain level of controls -- we'll see
11 these in your inspection reports -- like
12 barricades and locks and vaults and safes and
13 things of that nature?

14 A. Yes.

15 Q. Is that something that you looked
16 at when you did your pharmacy inspections?
17 Were you looking at things like personal
18 supervision and adequate safeguards for when
19 the pharmacy or pharmacist could not personally
20 supervise?

21 A. Yes.

22 Q. Okay. There's a provision of this
23 code on the third page -- I mean, of this
24 regulation, subsection (C).

25 Are you with me?

1 A. Yes.

2 Q. It says, a pharmacist, prescriber,
3 or responsible person for a terminal
4 distributor of dangerous drugs licensed
5 pursuant to 4729-5-11 of the Administrative
6 Code who has signed as being responsible for a
7 terminal distributor dangerous drug license is
8 responsible to monitor for suspicious orders,
9 unusual usage, or questionable disposition of
10 dangerous drugs.

11 What, in your experience, does
12 that mean?

13 A. Mean exactly what it says. They
14 should monitor for those things, suspicious
15 orders, unusual usage, questionable disposition
16 of dangerous drugs. I mean, it means what it
17 says. That's how I take it.

18 Q. Okay. Is that how you had it in
19 mind when you did your pharmacy inspections?

20 A. Yes.

21 Q. And is some or all of this part of
22 the DUR, the drug utilization review process?

23 A. Sure, it can be.

24 Q. Are there any other processes that
25 would encompass this section of the regulation

1 at a pharmacy, in your experience?

2 A. Can you expand on that? I
3 don't --

4 Q. Yeah. I'm just, you know, we've
5 gone over the security requirement and this --
6 it refers to this regulation. And this
7 subsection of the regulation speaks of
8 monitoring for suspicious orders or unusual
9 usage or questionable disposition.

10 In terms of when you went in to do
11 your pharmacy inspections, having this
12 regulation in mind, did you look for compliance
13 with this regulatory section in things like the
14 DUR, accessing OARRS, reviewing their systems,
15 and things of that nature?

16 A. Yes.

17 Q. Okay. There's a new security
18 requirement that went into effect recently, 3/1
19 of '20. I threw it in here just for reference.
20 It's 4729:5-3-14. Are you aware of there being
21 any significant change in the security
22 requirement effective 3/1 of 2020?

23 A. I don't know. I have not reviewed
24 the new code.

25 Q. Okay. Now, the other -- the last

1 code section in here is 4729-9-02, Minimum
2 Standards for a Pharmacy, and it's broken down
3 by library, equipment, stock of drugs,
4 prescription containers, space and fixtures,
5 pharmacy hours and personnel, and additional
6 minimum standards at the end.

7 I -- we'll see later in your
8 inspection reports there's reference to this
9 section. Is that something that you look for
10 as part of your inspections, compliance with
11 this code provision and, in particular, those
12 specific items that are listed here?

13 A. Yes.

14 Q. All right. Have you worked with
15 any of the pharmacy defendants' loss prevention
16 departments over the years?

17 A. I believe I've worked with all of
18 them.

19 Q. Have you worked with Giant Eagle's
20 loss prevention department, pharmacy --

21 THE WITNESS: I'm sorry. There's
22 some background noise. I don't know -- it
23 sounds like somebody's got a radio in the
24 background or something.

25 MR. BARNES: Yeah, can everybody

1 put on mute who's not talking, please?

2 THE REPORTER: It just got louder.

3 MR. THOMAS: I muted the person in
4 question.

5 MR. BARNES: Thank you. Can you send
6 them a scolding warning?

7 BY MR. BARNES:

8 Q. You said you've worked with all of
9 the pharmacy defendants' loss prevention
10 departments?

11 A. I believe so. CVS, Walgreens,
12 Walmart, Rite-Aid, and Giant Eagle; is that
13 the --

14 Q. Yes, yes. And have these loss
15 prevention departments assisted you in your
16 investigations and the Board's investigations
17 from time to time?

18 A. Yes.

19 Q. Have they provided information to
20 you concerning any -- the person under
21 investigation such as doctors and patients and
22 whoever you might be investigating?

23 A. Yes.

24 Q. Do you know Rick Shaheen at Giant
25 Eagle?

1 A. I do.

2 Q. Have you worked personally with
3 Mr. Shaheen over the years in investigations
4 involving pharmaceutical diversion?

5 A. Yes.

6 Q. Did you find Mr. Shaheen to be a
7 competent and diligent pharmacy loss prevention
8 person?

9 A. Yes.

10 Q. Was there ever a time that
11 Mr. Shaheen refused to cooperate with you or
12 the Board with respect to any investigation?

13 A. No.

14 Q. What about the other pharmacy
15 defendants, do you have similar views of their
16 pharmacy loss prevention departments?

17 A. Yes.

18 Q. Is it a good control to have a
19 pharmacy loss prevention department?

20 A. I think so.

21 Q. Do all pharmacies, in your
22 experience, have pharmacy loss prevention
23 personnel?

24 A. No.

25 Q. For example, independent

1 pharmacies, have you ever seen an independent
2 pharmacy have specific personnel assigned to
3 diversion, anti-diversion efforts?

4 A. No.

5 Q. Did Mr. Shaheen over the years
6 refer matters to you or call you from time to
7 time to report matters going on at Giant Eagle
8 Pharmacies?

9 A. Yes.

10 Q. And did you find him to be
11 informative and wanting to work with the Board
12 to stop diversion?

13 A. Yes.

14 Q. Did you ever advise Mr. Shaheen
15 with Giant Eagle generally -- you or the Board,
16 did you ever advise either of them that Giant
17 Eagle's loss prevention department needed to do
18 more or wasn't doing what it was supposed to be
19 doing?

20 A. I don't recall that.

21 Q. How about the other pharmacy
22 defendants, same question?

23 A. Not -- personally, no, I did not
24 do that. I don't know -- I can't speak for
25 other agents from our agency.

1 Q. Now, you referenced earlier the
2 licensing requirements of the Board, and I was
3 interested in that topic myself getting ready
4 for your deposition, so I took a look at the
5 different types of licenses that the Board
6 issues. One type of license is a terminal
7 distributor license. That's basically a
8 pharmacy license?

9 A. It's -- can be a pharmacy. It's
10 also a doctor's office. There's a number of
11 different entities that can be terminal
12 distributors.

13 Q. Okay. Okay. And do they have to
14 go through an application process and do they
15 have to be vetted, do they have to show their
16 qualifications, things of that nature, in order
17 to get a license?

18 A. Yes.

19 Q. And Exhibit 6 in your book shows
20 Ohio Revised Code 4729.54, Terminal Distributor
21 Licenses. Are you familiar with this code
22 provision and the requirements to get such a
23 license?

24 A. Yes. I mean, generally.

25 Q. Okay. So you can't operate as a

1 pharmacy or even a doctor's office distributing
2 controlled substances without going through the
3 Board licensing process, correct?

4 A. Correct.

5 Q. And you have to get that license
6 renewed from time to time and show continued
7 adherence to the Board's requirements; is that
8 right?

9 A. Yes.

10 Q. What -- Mr. Edwards, what are some
11 of the requirements that you can think of that
12 you, as an agent, saw and enforced when
13 individuals or entities were applying for a
14 pharmacy license? What are the main
15 requirements in your mind?

16 A. Well, the main requirements
17 initially prior to issuing the license, as an
18 agent, I would go out and conduct what we
19 called a barricade inspection.

20 Q. Okay.

21 A. Ensure that there was physical
22 security of the location and that it couldn't
23 be accessed by nonpharmacy employees at times
24 when the pharmacy staff was not there.

25 Q. Okay. So the barricade. Did you

1 look for anything else before the Board issued
2 the license? Was it just the barricade, or
3 were you looking at anything else?

4 A. There were other things like the
5 physical structure, you know, location, that
6 type of thing.

7 Q. Okay. Did you make sure that the
8 pharmacists to be employed were adequately
9 trained and licensed?

10 A. We did not do that as agents.
11 Like prior to issuing a license, we were just
12 making sure that the -- if you're talking about
13 licenses for pharmacies -- is that what you're
14 talking about?

15 Q. Yes. Yes.

16 A. Okay. So, no, we wouldn't --
17 oftentimes, when they were opening a new store,
18 for instance, they didn't know who the staff
19 was going to be, so that was not something that
20 we would necessarily do.

21 Q. Somebody else managed that in
22 terms of licensing the pharmacists; that, I
23 guess, would be the pharmacy licensing
24 personnel?

25 A. Well, yeah. They ensure that the

1 pharmacists are properly licensed.

2 Q. Okay. That's another part of the
3 Board, though, not necessarily inspection
4 agents?

5 A. Yes. Licensing is a whole
6 separate department.

7 Q. I see. Okay. And these -- in
8 Exhibit 6, besides Ohio Revised Code 4729.54,
9 there seem to be other provisions. .55 has the
10 licensing requirements. Are you familiar with
11 that code provision requiring, you know, proper
12 land, buildings, and equipment, licensed
13 pharmacists, adequate safeguards to prevent the
14 sale or other distribution of dangerous drugs
15 by any person other than a pharmacist or
16 licensed healthcare professional, adequate
17 safeguards that allows the pharmacist and
18 interns to practice in a safe and effective
19 manner? This is all part of the licensing
20 division's responsibilities and not you, as an
21 agent?

22 A. No. It's -- for instance, I mean,
23 I would have to review it and say it's a shared
24 responsibility to ensure that these
25 requirements are met.

1 Q. I see. So when you went out on an
2 inspection, did you have these requirements in
3 mind to make sure that the pharmacy was
4 complying with its license requirements?

5 A. Generally, yes.

6 Q. Okay. And the other code
7 provisions I attached here, 4729.551
8 essentially requiring the licensing of all
9 retail sellers, and then 4729.57, disciplinary
10 actions, did the Board retain the authority to
11 discipline pharmacies for violating any of its
12 rules or regulations?

13 A. Yes.

14 Q. And when you went out on your
15 inspections, were you specifically looking for
16 violations that might require disciplinary
17 action against the pharmacies?

18 A. We weren't specifically looking
19 for it, but if we found it, we would take
20 action.

21 Q. And --

22 MR. THOMAS: Mr. Barnes, I'm
23 sorry. What page is this on?

24 MR. BARNES: This would have been --
25 it's near the end of Exhibit 6. Page 11.

1 MR. THOMAS: Okay. Thank you.

2 MR. BARNES: It says 4729.57 at
3 the top.

4 BY MR. BARNES:

5 Q. And in your experience after doing
6 inspections, did you take action against
7 pharmacies for failing to comply with its
8 license requirements?

9 A. Occasionally.

10 Q. Okay. And 4729, the next two
11 pages later, is renewals. Did you understand
12 that pharmacies had to go through a renewal
13 process and prove that they were still in
14 compliance with all Board regulations?

15 A. I mean, they had to go through a
16 renewal process. I don't know that they
17 necessarily had to prove anything at that time
18 other than filling out their required
19 paperwork.

20 Q. I see. But between the time that
21 they get their original license and renew, they
22 are normally inspected by Board agents; is that
23 correct?

24 A. Yes. I mean, it varies from store
25 to store, but inspections occur on a routine

1 and also nonroutine basis.

2 Q. Does it mean anything in Ohio to
3 be licensed as a pharmacist? Is it a
4 significant thing to go through the licensing
5 process and get your license?

6 A. Sure.

7 Q. Now, we know that the pharmacists
8 who work in the pharmacy have to go through
9 certain licensing requirements and I gather
10 various Revised Code and OAC sections governing
11 the licensing of pharmacies. Do you recognize
12 these code sections, including the pharmacist
13 examination and qualifications requirements and
14 all the rules and renewal -- license renewal
15 things that they have to meet?

16 A. I recognize them. I wouldn't say
17 I'm familiar with all the substance, but I do
18 recognize them.

19 Q. I know from looking at your
20 inspection reports that the very first item
21 that is listed is something -- you know, are
22 all licenses properly displayed? Do you recall
23 that as part of your inspections?

24 A. Yes.

25 Q. You -- the Board wants every

1 pharmacy to show its license as well as the
2 pharmacists' licenses?

3 A. Yes. I don't believe that's still
4 a requirement, but it had been.

5 Q. Okay. Now, did you understand as
6 an agent that the practice of pharmacy is a
7 profession?

8 A. Yes.

9 Q. And are you familiar with the code
10 sections that specifically define what the
11 practice of pharmacy is and what pharmacist
12 care is? Are you familiar, for example, with
13 Exhibit 8, the code sections 4729.01?

14 A. Yes.

15 Q. There's a definition of the
16 practice of pharmacy. It means providing
17 pharmacist care requiring specialized
18 knowledge, judgment, and skill derived from the
19 principles of biological, chemical, behavioral,
20 social, pharmaceutical, and clinical sciences.
21 As used in this section, pharmacist care
22 includes the following: interpreting
23 prescriptions, dispensing drugs and drug
24 therapy-related devices, compounding drugs,
25 counseling individuals, performing drug regimen

1 reviews, performing drug utilization reviews,
2 et cetera.

3 Is that how you understood, when you
4 were inspecting pharmacies, that that's what is
5 meant to practice pharmacy?

6 A. Yes.

7 Q. Did your inspections involve
8 looking into how pharmacists were exercising
9 their professional judgment in any way?

10 A. Occasionally.

11 Q. How so? Can you describe that?

12 A. I mean, they -- we always
13 instructed them to use their professional
14 judgment when deciding whether or not to fill a
15 prescription or not fill a prescription.

16 Q. Okay. So that was something that
17 came up in the inspections from time to time?

18 A. Not -- maybe from time to time or
19 just, generally speaking, when we receive a
20 question or, you know, get a phone call from a
21 pharmacist.

22 Q. Okay. And part of this definition
23 of practice of pharmacy includes interpreting
24 prescriptions. What did you understand that to
25 mean when you were doing your pharmacy

1 inspections?

2 A. Reading the prescription,
3 interpreting what it means and what it says.

4 Q. There's actually a definition of
5 that term. It's right behind this first code
6 section 4729-5-01(D). It says -- it's about
7 four pages behind.

8 Are you with me?

9 A. Yep.

10 Q. It says, Interpret prescriptions
11 means the professional judgment of a pharmacist
12 when reviewing a prescription order of a
13 prescriber for a patient.

14 Is that how you understood the
15 term to mean, when they were interpreting
16 prescriptions, that there was a component of
17 professional judgment in there?

18 A. Yes.

19 Q. Now, pharmacists are not licensed
20 to prescribe drugs, correct?

21 A. Well, they are -- generally
22 speaking, no; however, there is a provision in
23 place now where they can prescribe with a
24 collaborating physician.

25 Q. When did that go into place?

1 A. Recently. I believe within the
2 last two years.

3 Q. And can they prescribe -- they
4 have to prescribe with a collaborating
5 physician, you said?

6 A. Correct.

7 Q. Do pharmacists have continuing
8 education requirements?

9 A. Yes.

10 Q. Does the Board licensing division
11 make sure that they comply with those
12 continuing education requirements?

13 A. Yes.

14 Q. Are the pharmacists authorized by
15 the Board or any other body, to your knowledge,
16 to practice medicine?

17 A. No, unless they're under that
18 collaborating physician.

19 Q. Can you tell me, is there a code
20 section for that collaborating physician?

21 A. I don't -- I don't know it off the
22 top of my head.

23 Q. Okay. Now, Mr. Edwards, you're
24 familiar with the code sections that deal with
25 how, from the Board's perspective, pharmacists

1 are to process a prescription; there are
2 specific code sections for that?

3 A. Yes.

4 Q. And I'll refer you to Exhibit 10.
5 Is this the OAC provision that governs how
6 pharmacists are supposed to process
7 prescriptions?

8 A. Yes.

9 Q. And are you familiar with this and
10 were you familiar with this provision when
11 doing your inspections?

12 A. Yes.

13 Q. Now, there are specific steps here
14 under section (B). A pharmacist when
15 dispensing a prescription must, and then
16 there's five items. Number 1, Ensure that the
17 patient information is profiled pursuant to
18 4729.5-18. Number 2, Perform prospective drug
19 utilization review pursuant to Rule 4729-5-20.
20 Number 3, Ensure that the drug is labeled
21 pursuant to Rule 4729-5-16. Number 4, Ensure
22 that a patient is given an offer to counsel
23 pursuant to 4729-5-22. And then, finally, the
24 fifth step is, Ensure that a prescription is
25 filed pursuant to Rule 4729-5-09.

1 Are those the steps that, in your
2 understanding, Ohio Board of Pharmacy lays out for
3 the pharmacist when dispensing a prescription?
4 These are the five specific steps?

5 A. Yes.

6 Q. Are you aware of any other
7 requirements that a pharmacist must follow
8 according to the Board other than these five
9 steps?

10 A. Not off the top of my head.

11 Q. What is a -- I'll take it a step
12 at a time. What does it mean for the patient
13 to be profiled? Patient information is
14 profiled?

15 A. They create a record of the
16 patient and the prescription.

17 Q. Each pharmacy does for each
18 patient?

19 A. Yes, for each prescription, each
20 patient.

21 Q. So step one is access that
22 information?

23 A. Correct.

24 Q. And step two is perform
25 prospective drug utilization review. Let's

1 shorthand that DUR so we don't have to keep
2 saying it.

3 A. Right.

4 Q. Perform a DUR. What does it mean
5 to perform a DUR?

6 A. That's to ensure that, you know,
7 there's not duplicate therapy or
8 overutilization or -- it's basically steps they
9 take to check to make sure the patient should
10 get that prescription and it's okay to fill it.

11 Q. Okay. And is that, in your
12 experience, normally part of the pharmacy's
13 software system when filling a prescription?

14 A. Yes. If there's a DUR warning, it
15 will pop up on their screen typically.

16 Q. All right. And the Board expects
17 pharmacists to check the DUR warning if it
18 comes up?

19 A. Correct.

20 Q. Okay. Number -- the step three
21 is, ensure the drug is labeled. And what does
22 that mean?

23 A. That there's a label on the
24 medication vial stating what it is, what's in
25 it, expiration date, those types of things.

1 Q. And that's something you look at
2 in your inspections, correct? You check to see
3 if prescriptions were getting properly labeled
4 before dispensing?

5 A. Sure.

6 Q. And the DUR review, did you also
7 check for DUR reviews in your inspections?

8 A. Occasionally, yes.

9 Q. Okay. And patient profiling, is
10 that also something you checked for in your
11 inspections?

12 A. Yes.

13 Q. All right. The fourth step is the
14 offer to counsel. I saw reference in some of
15 your inspection reports to checking the
16 counseling logs.

17 A. Yes.

18 Q. Is that seeking to determine
19 compliance with this provision?

20 A. Yes, it is. Yes.

21 Q. All right. And then the fifth
22 step is ensuring the prescription is filed.
23 Does that -- is that a recordkeeping function
24 to make sure that you can go back to the
25 prescription and take a look at it --

1 A. Yes.

2 Q. -- for whatever reason?

3 A. Correct.

4 Q. Is that something you checked for
5 in your inspections?

6 A. Yes.

7 Q. Now, each of these five steps
8 refers to another provision. And I attached
9 them right behind code section 5-21. The first
10 one is 5-18. That's the patient profile. And
11 the Board requires, according to this
12 regulation, that the pharmacy have patient --
13 certain amount of patient information in its
14 profiles, correct?

15 A. Correct.

16 Q. And in your inspections, would you
17 check to make sure that the pharmacy's patient
18 profile met this requirement?

19 A. Yes.

20 Q. And then the next code section is
21 5-20. This is the prospective DUR. We talked
22 about that before. You gave me some of this
23 information. Overutilization,
24 underutilization, therapeutic duplication, et
25 cetera. Is that an important part of what the

1 Board wanted the pharmacies -- or pharmacists
2 to do before dispensing?

3 A. Yes.

4 Q. And then the next provision, 5-16,
5 is the labeling. This appears to impose
6 specific labeling requirements on each
7 prescription, including name and address of the
8 pharmacy, full name of the patient, full name
9 of the prescriber, directions for use. Is that
10 something that you checked for in your
11 inspections?

12 A. Yes.

13 Q. And then, finally, 5-22 is the
14 patient counseling. We talked about that
15 already. You told me you checked for that.

16 And then 5-09 appears to be a -- the
17 prescription filing requirement setting forth
18 specific ways in which prescriptions for certain
19 controlled substances had to be filed, including
20 control IIs had to be in a separate file,
21 correct?

22 A. Correct.

23 Q. When you went in for your
24 inspections, would you ask for the control II
25 file to make sure they were complying with this

1 type of thing?

2 A. Yes.

3 Q. Now, we know from having discussed
4 OARRS already that there's also a check OARRS
5 requirement that evolved over time, right?

6 A. Correct.

7 Q. So in addition to these five
8 steps, there's also a separate provision saying
9 check OARRS when certain conditions are met,
10 correct?

11 A. Correct.

12 Q. Now, is there anything else from
13 the Board's perspective that a pharmacist was
14 required to do besides these five steps and
15 checking OARRS that you can think of based on
16 your experience as an agent?

17 A. Not off the top of my head.

18 Q. Okay. Did the Board ever provide
19 any specific instructions to pharmacies beyond
20 this regulatory section that said, we want you
21 to do more than what's in this regulation for
22 whatever reason? Can you think of anything
23 that the Board ever said or issued the
24 pharmacists saying, do more than what's in 5-21
25 and checking OARRS? Can you think of anything?

1 A. Maybe like a newsletter or
2 guidance document or something like that,
3 maybe.

4 Q. Okay. Go back to 5-20, the
5 prospective DUR. This section, we touched on
6 it, but I forgot to go over (B) and (C) and
7 (D). I think -- this is the DUR stuff. But
8 subparagraph (B) talks about pharmacists using
9 professional judgment shall take appropriate
10 steps to avoid or resolve a potential -- the
11 potential problem. And then the preface to
12 that is upon identifying any issue listed in
13 paragraph (A). These steps may include
14 requesting and reviewing an OARRS report or
15 other state's report pursuant to subparagraph
16 (D) and/or consulting with the prescriber
17 and/or counseling the patient.

18 Is that how you understood the
19 DUR, to not only be -- consider the factors in
20 (A), but if you spot an issue, use your
21 professional judgment, which may involve
22 checking OARRS and talking to the doctor?

23 A. Yes.

24 Q. Okay. Is there any requirement in
25 (A) or (B), specifically (B), that requires the

1 pharmacist to record everything he or she does
2 if he follows up -- he or she follows up on any
3 of the information in (A)? In other words, is
4 there anything here that says, and if you do
5 call the doctor, it must be in writing and it
6 must be kept, you know, for a certain period of
7 time?

8 A. I don't see that in here.

9 Q. Are you aware of any requirement
10 by the Board that required pharmacists to
11 document or retain things that the pharmacist
12 was doing in the exercise of their professional
13 judgment as part of their DUR?

14 A. Well, I mean, it's part of the
15 recordkeeping, I guess. I always tell people,
16 if you don't write it down, it didn't happen.
17 So it's -- I don't know if there's a specific
18 rule or law that says it has to be done, but I
19 take it to mean, if they do something, if they
20 take an action, that it should be memorialized
21 either in the patient chart or, you know, the
22 patient profile or somehow in the record or on
23 the prescription even.

24 Q. But you seem to be referring to
25 something that's outside the regulation?

1 A. I don't see it -- I don't see it
2 here. I don't know if it's in another
3 regulation or not.

4 Q. Okay. Subsection (D) -- I'm
5 sorry -- (C) refers to using -- as part of your
6 DUR, you use predetermined standards consistent
7 with but not limited to any of the following:
8 peer-reviewed medical literature, American
9 hospital formulary, service drug information,
10 and United States pharmacopeia drug
11 information.

12 What do you understand this provision
13 of the DUR regulation to mean?

14 A. That they should check their
15 resources, for instance, regarding drug
16 therapies. I mean, that's what these -- that's
17 what these publications are for.

18 Q. All right. So the regulation
19 actually directs the pharmacist to go to these
20 sources when doing a DUR if necessary?

21 A. These or others.

22 Q. Okay. And then (D) of this
23 regulation --

24 A. Yes.

25 Q. -- section (D) says, Prior to

1 dispensing an outpatient prescription for a
2 reported drug, pharmacist shall request and
3 review an OARRS report covering a one-year time
4 limit in the following circumstances, which I
5 think we've already covered.

6 Do you see that there's the same
7 steps we previously talked about, it's a new
8 drug, no report in the last 12 months,
9 prescriber located outside usual pharmacy
10 geographic area, patient is outside the -- the
11 patient is from outside the usual geographic
12 area, et cetera; we've covered these before?

13 A. Yes.

14 Q. So this is the actual regulation
15 that imposes those requirements?

16 A. Correct.

17 Q. Now, this regulation, as I think
18 we've talked about before, the actual
19 regulation doesn't talk about any specific
20 geographic area, correct? It doesn't limit it,
21 it doesn't say use X number of miles, and
22 that's because it's a subjective fact-specific
23 situation for each pharmacy, correct?

24 A. Correct.

25 Q. All right. And then, similarly,

1 when it says check OARRS when you have reason
2 to believe that the patient has received
3 prescriptions for reported drugs for more than
4 one prescriber in the preceding three months
5 unless the prescriptions are from prescribers
6 who practice in the same location -- physical
7 location, that's -- that's a requirement that
8 the Board imposes, but that's a subjective
9 thing, also, correct?

10 A. Well, I don't think it's
11 subjective because it's saying if they have
12 reason to believe that they obtained
13 prescriptions from someone else. So if -- I
14 take that to mean, if they come upon this
15 knowledge, that they will check it.

16 Q. I see. Because I guess I'm
17 thinking about that type of information is in
18 OARRS, but this is a listing of when you should
19 go check OARRS. So is it your understanding
20 that if they -- if from outside OARRS they
21 obtain this kind of information, they should
22 check OARRS?

23 A. Correct. Like if the patient
24 says, I used to see Dr. So-and-so and get
25 whatever drug, but now I'm getting this, then

1 that would fall under that category.

2 Q. Okay. And then the last one -- I
3 think it's the last one -- we've seen this
4 before. Patient is exhibiting signs of
5 potential abuse or diversion. And we've talked
6 about that, that's the subjective one, kind of
7 depends upon professional judgment at the time
8 of dispensing?

9 A. Yes. Some of those factors could
10 be subjective, professional judgment, and then
11 some could be overt observations.

12 Q. Has the Board ever issued to
13 pharmacies or pharmacists formulas or
14 algorithms that say, you know, do not dispense
15 if this formula's met or cut a patient off
16 under these circumstances? Has that ever
17 happened, in your experience?

18 A. Not to my knowledge.

19 Q. And why is that? What's your
20 understanding of why that would be?

21 A. Well, each incident is unique and
22 there are different factors involved in each
23 patient and each prescription and each
24 interaction at the pharmacy, and different
25 factors should be taken into account. So I

1 don't think one in and of itself would be, you
2 know, reason to issue an edict like that.

3 Q. In order to determine whether or
4 not a prescription was legitimate, would you
5 need to know what the prescriber's purpose and
6 intent was behind the prescription?

7 MR. CIACCIO: Objection to form.

8 A. Can you rephrase that?

9 BY MR. BARNES:

10 Q. Sure. In order to determine
11 whether a prescription is legitimate at the
12 point of dispensing, would you need to know
13 more than what is shown on the prescription
14 itself as well as what's in OARRS or the DUR
15 process; in other words, is there missing
16 information? If somebody says is this a
17 legitimate prescription, the information you
18 critically need would be from the doctor, what
19 did the doctor -- why did they issue the
20 prescription, for what purpose after performing
21 what examinations, et cetera? That's my
22 question.

23 MR. CIACCIO: Same objection to form.

24 A. Well, I think -- can you define
25 legitimate prescription for me?

1 BY MR. BARNES:

2 Q. Sure. Whether or not a
3 prescription is valid, i.e., was properly
4 prescribed by a physician for a medical purpose
5 based upon a medical diagnosis.

6 A. I guess --

7 Q. In order --

8 A. I guess the best way for me to
9 answer that is to say, there are times after a
10 prescription is filled that it can be
11 determined, you know, there's more -- I guess
12 I'm not -- I'm not really sure how to answer
13 that because, I mean, when a prescription is
14 presented and a pharmacist goes through all
15 these, you know, DUR requirements, are you --
16 are you asking what if there's other
17 information they're missing? I mean --

18 Q. Well, let me break it down for
19 you. What I have in mind is the testimony of
20 Chad Garner when he was talking about OARRS.

21 A. Okay.

22 Q. He told us that OARRS does not
23 evaluate patient data and red flag certain
24 patients because, even today, we would not have
25 all of the history that a healthcare

1 professional would have about their case to
2 know, you know, what other diagnosis the
3 patients may have, what other circumstances
4 there may be. We are really dealing just with
5 a list of prescriptions, which is not the
6 entire picture.

7 So my first question is, do you agree
8 with that position with respect to the data that's
9 in the OARRS database, that you can't -- you can't
10 tell whether or not --

11 A. Right.

12 Q. It's just data, right?

13 A. It's -- right. It's a piece of
14 the puzzle. It's not -- just like the
15 prescription is a piece of the puzzle and the
16 patient's chart is a piece of the puzzle. And
17 nobody has access to all those -- all of that
18 data at any, you know, one time.

19 So like a pharmacist filling a
20 prescription that they believe -- they do their
21 professional judgment and they believe it meets
22 all these parameters set forth still would not
23 have access to the patient chart or to the
24 patient's medical history. They may have
25 access to the prescription history, but they

1 don't have access to their medical chart and
2 that sort of history.

3 Q. So -- okay. I didn't mean to cut
4 you off.

5 A. No, that's okay. So I guess it's
6 a very complex question. So that's why I guess
7 I'm not really sure how to answer it. For
8 instance, if the patient brings in a
9 prescription that interacts with some medical
10 condition they have and that doctor didn't know
11 it because the patient didn't tell them and the
12 pharmacy didn't know it, well, that
13 prescription is still legitimate even though,
14 with all the information, it would be
15 contraindicated and should not have been
16 prescribed.

17 Q. Right. So my follow-up question
18 is, if it later -- if later there's an inquiry
19 made as to legitimacy of a prescription, in
20 order to get the complete picture, you can't
21 just go back to the pharmacy and say, show me
22 this prescription, you would need to backtrack
23 and go back to the medical provider, the
24 prescriber, and say, why did you issue this,
25 for what purpose, what condition, et cetera?

1 MR. CIACCIO: Objection.

2 A. Correct.

3 BY MR. BARNES:

4 Q. Okay. Mr. Edwards, you performed
5 a lot of inspections over your career so far
6 with the Board of Pharmacy; am I correct?

7 A. Yes.

8 Q. Approximately how many inspections
9 would you say that you've performed?

10 A. Well, hundreds, if not thousands;
11 much less in the last three years since I've
12 been working on the intervention program, but
13 prior to that, from 2008 till 2018, so for ten
14 years I was doing probably 50 or so inspections
15 a year.

16 Q. 50 a year for about nine or ten
17 years?

18 A. Correct. Approximately. And
19 maybe more.

20 Q. Let's just call it hundreds. How
21 about that? Hundreds?

22 A. Okay.

23 Q. Well, we know that you've
24 inspected Giant Eagle Pharmacies. If you look
25 at Exhibit 14. The Board produced to us

1 inspection reports for all pharmacies in Lake
2 and Trumbull County.

3 A. Uh-huh.

4 Q. And this is a spreadsheet that
5 I've had prepared. I wanted to know who did
6 what inspections in which counties, and you're
7 listed the number one -- on that line one, row
8 one as having performed 23 inspections of Giant
9 Eagle Pharmacies in Lake County and three in
10 Trumbull County.

11 Does that seem accurate to you?

12 A. Sure.

13 Q. And then Mr. Pavlich is listed as
14 performing none in Lake County and 21 in
15 Trumbull County. And I think you told me
16 earlier, because he was assigned more to that
17 geographic region than you?

18 A. Correct. Correct.

19 Q. All right. And you can see that
20 the Board produced 93 inspections -- this is
21 just of Giant Eagle Pharmacies -- in the time
22 period, which is 2006 to 2019. So almost 100
23 times Giant Eagle Pharmacies were inspected by
24 the Board, 26 of which were you, 21 of which
25 were Mr. Pavlich, and then others. Is that, in

1 your experience, the approximate amount of
2 frequency that a chain pharmacy in these areas
3 was inspected in this time period?

4 A. I couldn't say. There's -- each
5 chain has a different number of pharmacies, you
6 know, some more than others. So I couldn't
7 answer that.

8 Q. Okay. Were pharmacies -- how were
9 they selected for inspection and for what time
10 periods? Were these like cyclical inspections,
11 you try to get out there every year, every 18
12 months, every two years?

13 A. Yes. I would say initially, when
14 I was first hired, I was doing inspections at
15 all my sites every year. And then additional
16 ones if there were issues, you know, if there
17 was an error at the pharmacy or if there was a
18 criminal investigation at the pharmacy, an
19 additional inspection may also take place.

20 Q. Okay. And so they began
21 approximately every year. Did they -- for the
22 routine inspections, did they get longer over
23 time, like 18 months, two years?

24 A. It just varied. I mean, it varied
25 based on caseload and, you know, the agent's

1 geographic area. Some agents had bigger areas
2 and couldn't get to as many sites as -- you
3 know, as other agents.

4 Q. Now, I saw from your inspection
5 reports -- and if it helps you, you can flip to
6 Exhibit 15. Exhibit 15 is a compilation of all
7 of the inspection reports prepared by you for
8 Giant Eagle Pharmacies in Lake and Trumbull
9 Counties.

10 A. Okay.

11 Q. And off to the left of these
12 inspection reports down at the bottom, when I
13 first read those, the Fs and the Ps, I was
14 reading those as --

15 A. Pass or fail.

16 Q. -- pass or fail. And then that
17 was clarified for me later that that actually
18 means full inspection versus partial
19 inspection?

20 A. Correct.

21 Q. Okay. I was glad to learn that.

22 So what determined a full inspection
23 versus partial?

24 A. That was kind of a subjective
25 measure. A full inspection would mean we would

1 go over the majority of items on that left side
2 that are listed there. A partial -- generally
3 speaking, a partial would be where you go in
4 and you're just doing a barricade inspection or
5 you're just --

6 Q. I see.

7 A. -- you know, getting a
8 prescription and, therefore, you know, you're
9 only looking at a few of the items on that
10 list.

11 Q. All right. Before we dive in, I
12 wanted to look at the regulatory background of
13 these inspections beginning with Exhibit 11.
14 Why don't you take a look at 11? Do you
15 recognize this as the OAC section authorizing
16 the Board to conduct onsite inspections --
17 unannounced onsite inspections of all
18 licensees?

19 A. Yes.

20 Q. And so that was a right that the
21 Board had as a condition of getting and
22 renewing your license?

23 A. Correct.

24 Q. And were the majority of your
25 inspections, were they unannounced; in other

1 words, you didn't call the pharmacy and say,
2 I'm going to be there a week from Tuesday, get
3 ready?

4 A. Correct.

5 Q. And is there --

6 MR. THOMAS: Mr. Barnes, I'm
7 sorry. What's the Bates number on this page?

8 MR. BARNES: It's Exhibit 11.

9 MR. THOMAS: That's why I don't
10 see it.

11 MR. BARNES: Yeah. Sorry.

12 BY MR. BARNES:

13 Q. This code section says, Pursuant
14 to section 3719.13 of the Revised Code, an
15 entity licensed by the State Board of Pharmacy
16 as a terminal distributor of dangerous drugs is
17 subject to an onsite inspection by the Board.
18 An authorized Board agent may, without notice,
19 carry out an onsite inspection or investigation
20 of an entity licensed by the Board. Upon
21 verification of the Board agent's credentials,
22 the agent shall be permitted to enter the
23 licensed entity.

24 Now, that's your regulatory
25 authority, correct, to show up unannounced at

1 pharmacies and say, I'm doing an inspection,
2 correct?

3 A. Yes.

4 Q. And do you recall doing
5 inspections of pharmacy defendants' stores?

6 A. Yes.

7 Q. And do you recall presenting your
8 credentials to the pharmacists and saying, I'm
9 here to do an inspection?

10 A. Yes.

11 Q. And with respect to the pharmacy
12 defendants, were they cooperative and allowed
13 you to do your inspections?

14 A. Yes.

15 Q. When you did an inspection, were
16 you allowed access by the pharmacy defendants
17 to any and all records that you wished to see
18 in the pharmacies?

19 A. Yes. Any and all that they had in
20 the pharmacies, and if there were records
21 outside the pharmacy, I could request that.

22 Q. And when you performed your
23 inspections, at least after OARRS was created,
24 the Board had within its body of knowledge all
25 of the prescriptions filled by that pharmacy

1 for any period of time leading up to the
2 inspection; is that correct?

3 A. No. Are you talking about OARRS
4 prescriptions? Or like --

5 Q. Yeah. I may have misstated my
6 question. Let me strike that. I'll rephrase
7 the question.

8 After OARRS was created and all
9 pharmacies had to provide their daily
10 prescription dispensing records to the Board,
11 my question is, when you -- after that OARRS
12 was created and you had that information, when
13 you showed up for those inspections, that was
14 part of the information that the Board had with
15 respect to the pharmacy to be inspected,
16 correct?

17 A. Correct. That was in our OARRS
18 database, yes.

19 Q. Okay. And the general purpose of
20 your inspections was to make sure that the
21 pharmacy continued to meet the licensing
22 requirements set by the Board, correct?

23 A. Correct.

24 Q. This code section in Exhibit 11,
25 5-3-03, part (B) says, Submission of an

1 application for a license as a terminal
2 distributor of dangerous drugs with the State
3 Board of Pharmacy constitutes permission for
4 entry and onsite inspection by an authorized
5 Board agent.

6 So by merely applying for a
7 license, you had to consent to allow agents to
8 come in at any time?

9 A. Correct.

10 Q. All right. And then subsection
11 (C) of this regulation says if you find a
12 violation during the inspection, the agent may
13 provide written notice of the violations to the
14 pharmacy, correct?

15 A. Correct.

16 Q. And the process was -- was it your
17 practice to -- if you found a violation, to
18 write it up on the inspection report and tell
19 the pharmacy, give us a written response within
20 a certain period of time?

21 A. Correct.

22 Q. Okay. And if you found
23 violations -- the violations, according to this
24 regulation, may include -- and this is part
25 (D) -- any of the following: violating any

1 rule of the Board, violating any provision of
2 Chapter 4729 of the Revised Code, violating any
3 provision of the Federal Food Drug and Cosmetic
4 Act, violating any provision of the Federal
5 Drug Abuse Control laws or regulations. That's
6 the type of violations you could write up a
7 pharmacy for if you saw it during your
8 inspection, correct?

9 A. Yes.

10 Q. And did you actually in your
11 career write up pharmacies for violating any or
12 all of these laws?

13 A. Yes.

14 Q. And then, finally, this regulation
15 requires in subsection (E), The licensee or
16 applicant shall submit to the Board within 30
17 days of a written notice provided in accordance
18 with paragraph (C) in a manner determined by
19 the Board either of the following: the actions
20 the licensee or applicant has taken to correct
21 the violations and the date of implementation
22 of the corrective actions or an explanation
23 disputing the violations.

24 Is that how you did your
25 inspections in connection with this regulation?

1 A. Yes.

2 Q. Now, did you -- did the Board have
3 a so-called -- I'll just call it an inspection
4 guide for pharmacies?

5 A. Not --

6 Q. Did you follow -- was there a
7 guide that you guys had, the agents had when
8 you went out to do your inspections?

9 A. For the vast majority of my
10 inspections, no. That's a fairly new creation.
11 We went digital. When inspections became
12 digital, there was an inspection guide
13 installed in our inspection software. But when
14 we did the paper inspections like the first one
15 in Exhibit 15 here, there was no -- there was
16 no published guide.

17 Q. I see. And there was no internal
18 unpublished guide either?

19 A. No. I mean, different people had
20 spreadsheets of different rules and stuff to
21 look at, but there was no -- I mean, there
22 was -- there were different documents floating
23 around. I don't recall if any of them were
24 specifically Board issued, but in terms of a
25 guide, a published guide, that all came when we

1 went online, when inspections were starting to
2 be completed electronically.

3 Q. When was that, approximately?

4 A. Probably four or five years ago, I
5 guess. I don't recall the exact date.

6 Q. So maybe 2015 or so?

7 A. Maybe. Maybe '14, '15, somewhere
8 like that.

9 Q. Okay. Have you had an opportunity
10 to look at this inspection guide? And I'll
11 tell you, I got it from the Board website.

12 A. Yeah.

13 Q. And I kept digging for something
14 prior to 9/23 of '20, but you've now explained
15 why it's not available; it's because there
16 wasn't one?

17 A. Right.

18 Q. Correct.

19 A. Like a lot of things at the
20 agency, it has evolved to the point where it's
21 at now.

22 Q. All right. In looking through
23 this guide, it has a nice summary of all the
24 code and administrative regulations. And then
25 it has a page 11 of Exhibit 12. It has a table

1 of contents which refers to sections of the
2 code -- sections of the manual dealing with
3 each specific part of an inspection. Do you
4 see that? Paragraph -- page 11 of Exhibit 12.

5 A. Yes.

6 Q. Okay.

7 A. I see that.

8 Q. Are these, this listing, which
9 continues onto 12, are these the areas
10 inspected when you did a full inspection?

11 A. This is some of the areas. We
12 didn't necessarily inspect every single item.
13 However, these are -- this is a listing of
14 them.

15 Q. All right. So the fact that this
16 is a 2020 inspection manual, what I'm getting
17 at is, it doesn't mean it's entirely irrelevant
18 to what we're doing?

19 A. Correct.

20 Q. These are areas that you actually
21 did inspect in your discretion, correct?

22 A. Correct.

23 Q. All right. Have you had an
24 opportunity to flip through this manual and get
25 an understanding of whether or not it's

1 anything new that you weren't familiar with?

2 A. Well, this -- this is new. In
3 fact, this is just -- the outpatient inspection
4 guide is something that was newly created.
5 So --

6 Q. Okay.

7 A. -- I'm familiar with items within
8 it, yes. Am I familiar with the specific
9 guide? I would say not entirely.

10 Q. Okay. All right. We may refer
11 back to it if necessary, but you've already
12 answered my question concerning this was a part
13 of your inspections.

14 The regulations issued by the
15 Board include specific requirements for
16 controlled substance inventories, correct?
17 And, if so, is that shown in Exhibit 13?

18 A. Yes.

19 Q. And am I correct in my summary of
20 these requirements that pharmacists -- or
21 pharmacies were supposed to have an annual
22 inventory of controlled substances at a
23 minimum?

24 A. That's -- that's a recent change.
25 It used to be biannual. It changed to annual

1 within the last couple years, I believe.

2 Q. All right. So prior to a couple
3 years ago, it was every two years?

4 A. Yes.

5 Q. And now it's every year?

6 A. Correct.

7 Q. And have you experienced during
8 your inspections pharmacies doing it more
9 frequently as a better internal control?

10 A. When it was required to be done
11 every two years, there were pharmacies who did
12 it every year. So yes.

13 Q. And did you consider that a good
14 control?

15 A. Yes.

16 Q. Do you recall specifically any of
17 the pharmacy defendants inventorying -- how
18 often they inventoried controlled substances,
19 or would you need to see the inspection reports
20 to know that?

21 A. I'd have to read them. I don't
22 recall the time frames.

23 Q. All right. With respect to
24 Exhibit 15, this is the compilation of your
25 inspection reports for Giant Eagle. I want to

1 understand these reports a little bit.

2 When you went out to do
3 inspections of pharmacies, did you refresh your
4 memory regarding the prior inspection of that
5 pharmacy, whether you did it or somebody else
6 did it?

7 A. I oftentimes -- I don't know if I
8 did it every time, but often I would.

9 Q. Okay. Do you recall specifically
10 inspecting Giant Eagle Pharmacies in Lake and
11 Trumbull County?

12 A. I recall, yes.

13 Q. On a general basis, do you recall
14 the inspections generally being favorable in
15 terms of Giant Eagle's pharmacies were doing
16 what they were supposed to be doing under the
17 Board rules?

18 A. Yes, generally.

19 Q. Is that true of the other pharmacy
20 defendants, did they -- did their inspections,
21 to your knowledge, generally -- were they
22 generally favorable from the Board's
23 perspective?

24 A. Yes.

25 Q. When you did the inspections and,

1 again, Giant Eagle specific, in Lake and
2 Trumbull County, beginning with this first
3 inspection -- we'll take that as an example --
4 this was of 2/4 of '09, store number 6377, in
5 Painesville Township, Ohio. You inspected
6 that store five times. Do you remember
7 working with the pharmacist at that store,
8 Mr. Robert Hytree?

9 A. Yes, I remember Mr. Hytree.

10 Q. And was Mr. Hytree generally
11 cooperative with you and provide you access to
12 any and all information you wanted as part of
13 your inspection?

14 A. As far as I recall.

15 Q. Now, this form that this
16 inspection is on, there's a list of items 1
17 through 40 and some of them are circled?

18 A. Yes.

19 Q. And I was trying to track what
20 those circlings meant, et cetera. What did you
21 intend them to mean when you circled these
22 items?

23 A. That was the items that I looked
24 at. The small circle -- circling the numbers,
25 that was an item that I looked at. The larger

1 circles were -- you know, where I circled the
2 entire phrase was an item that had an issue
3 that required response.

4 Q. Okay. And whenever you had an
5 item at issue for Giant Eagle Pharmacies that
6 required a response, did you get that response?

7 A. I recall -- generally, I recall
8 that I did. I don't recall any instances where
9 I did not.

10 Q. And -- now, here you've circled
11 licensing, outdated drugs, RX information, and
12 refills-INT/date. Were these the items you
13 wanted Mr. Hytree to follow up because you
14 found some areas that required follow-up?

15 A. Yes.

16 Q. All right. Now, was it in your
17 discretion to not look at certain items like
18 15, 16, and 17; there's nothing there? Is that
19 just something that the agent can say I'm going
20 to look at it or I'm not going to look at it?

21 A. Correct.

22 Q. But would you over time want to
23 make sure that you looked at all of these items
24 after multiple inspections?

25 A. I can't answer that.

1 Q. Okay. But you certainly had the
2 right, going into an inspection, to look at any
3 of these items 1 through 40, correct?

4 A. Correct.

5 Q. And it wasn't up to the pharmacist
6 to say to you, no, you're not looking at these
7 items, you're only going to look at these other
8 items?

9 A. Right.

10 Q. Correct?

11 A. That never happened.

12 Q. And what was your thinking when
13 you selected what to look at? What were you --
14 how did you make that selection, I'm going to
15 go to this pharmacy on this day, do an
16 unannounced inspection, and I'm going to look
17 at the following factors? How was that
18 determined? Was it based upon your knowledge
19 of the pharmacist or the pharmacy or things of
20 that nature?

21 A. Yes, a bunch of factors. I mean,
22 I don't think there was any -- there was not
23 any one thing that made me decide to look at
24 certain things or not look at certain things.

25 Q. Okay. We know from this

1 inspection 2/4/09 that, for example, number 3
2 is the records system, and then you list in
3 handwriting off to the right, PDX software
4 version 4.6.07, pharmacy uses a realtime
5 dispensing system which is connected to all
6 Giant Eagle stores.

7 So one of the things you looked at
8 during your inspection was the type of dispensing
9 system that they used?

10 A. Yes.

11 Q. And was it an indication to you of
12 a good internal control that the pharmacy was
13 using the certain software system with certain
14 number of terminals and they were
15 interconnected with each other?

16 A. Yes. Because some are approved --
17 different software systems had to be approved
18 for use by our agency.

19 Q. All right. And at this
20 inspection, Giant Eagle was using an approved
21 software system?

22 A. Yes.

23 Q. And that system had a 7-point
24 check verification system which the pharmacists
25 used and the techs used to prevent errors. You

1 wrote that in your report?

2 A. Correct.

3 Q. And they actually used -- you
4 reference, patient profile recall available for
5 at least two years at store.

6 That's what the Board wanted,
7 right?

8 A. The two-year recall of the patient
9 data. We wanted 12 months. I believe 12
10 months is what was required.

11 Q. So Giant Eagle was doing more than
12 what the Board required?

13 A. Two years, correct.

14 Q. And then on page 2, it says,
15 pharmacists use a barcode verification system
16 followed by a password for final verification
17 at two of the five work stations.

18 Is that a good internal control,
19 barcode verification systems and passwords as
20 part of the dispensing process?

21 A. Sure.

22 Q. All right. So with respect to
23 this inspection, you found the recordkeeping
24 system to be not only adequate, but in some
25 ways more than adequate; is that right?

1 A. You mean more than adequate
2 because they kept two years' worth of --

3 Q. Yeah, that's what I was referring
4 to.

5 A. Yes.

6 Q. Okay. And another factor you
7 looked at, I forgot to go over. The number one
8 item at the top, you say, Board and DEA license
9 are current and posted, TDDD license is posted,
10 however, pharmacist license wall certificates
11 are not posted.

12 So you found that to be an issue
13 that required follow-up?

14 A. Correct.

15 Q. You wanted that -- those things on
16 the wall. And Giant Eagle followed up as you
17 requested, correct?

18 (Technical interruption.)

19 A. The answer was, he asked if they
20 responded to those, so I was flipping to the
21 page where, yes, they responded.

22 BY MR. BARNES:

23 Q. Yeah, go to 2327. That's where
24 the response is.

25 A. Yes.

1 MR. BARNES: Who's ever tapping,
2 please turn your microphone off, mute yourself,
3 please. Thanks.

4 BY MR. BARNES:

5 Q. So continuing, some of the other
6 things you looked at were barricade, which you
7 described for us. And that's not listed as a
8 follow-up item, so that means it was
9 satisfactory, correct? You say, fully enclosed
10 barricade, see barricade inspection report?

11 A. Yes, that was the last page of the
12 report.

13 Q. Okay. And I'm starting to
14 understand these a little bit better. Number 6
15 is security. What did you look at in terms of
16 security in these inspections?

17 A. The physical alarm system to see
18 if they had an alarm system with motion sensors
19 or not or if they just had a key lock system
20 that only the pharmacist possessed the keys.

21 Q. Okay. So in this inspection,
22 security met the requirements, you didn't
23 require any follow-up, correct?

24 A. Correct.

25 Q. And these other items, library,

1 you mentioned that, that doesn't have any
2 follow-up, so I assume that was met. Same with
3 cleanliness, refrigeration, and accountability?

4 A. Correct.

5 Q. All satisfactory from the Board's
6 perspective?

7 A. Correct.

8 Q. Accountability refers -- you write
9 up DEA 222 forms in proper order, forms are
10 properly filled out and signed when control II
11 order received. No wholesale sales being made.

12 So the accountability issue is --
13 sounds like it's whether they have proper records
14 for how they're handling controlled substances?

15 A. Right.

16 Q. Okay. It looks like here you
17 found an outdated drug on the shelf; is that
18 right? You checked the prescription, a certain
19 prescription, and you found that it had an
20 expiration date the month prior to dispensing,
21 correct?

22 A. Yes.

23 Q. And you asked for follow-up on
24 that. And the pharmacist did follow up on page
25 2327. Am I right?

1 A. Yes.

2 Q. Now, for number 32, that was
3 something you asked for follow-up. You had a
4 refill issue and on page 2319 you say that the
5 pharmacy generates an end-of-day report that
6 lists all Rx's dispensed that day by pharmacist
7 initials. Each dispensing pharmacist who
8 worked that day must take accountability for
9 the prescriptions they dispensed by signing a
10 daily log that lists all refills. Currently
11 pharmacists sign a cognitive services report
12 that does not list all refill prescriptions.
13 And then you go on to say that that's not quite
14 how you want it done. Am I right?

15 A. Correct.

16 Q. And you asked Giant Eagle to
17 change their practices, and in their response
18 they would?

19 A. Yes.

20 Q. Correct. All right. So that
21 issue was resolved. And then your
22 inspection -- is there any indication on your
23 inspection something simple like pass/fail
24 or --

25 A. No.

1 Q. -- is it you just got to read it
2 and --

3 A. No, it's either corrective action
4 required or not.

5 Q. All right. So after you
6 identified four issues and Giant Eagle
7 responded, were you satisfied your inspection
8 issues had been addressed and, therefore, the
9 inspection was a successful one as resolved?

10 A. I believe so, yes.

11 Q. Okay. Did that happen often with
12 the Giant Eagle Pharmacies, that you would find
13 items that you wanted follow-up on, they would
14 follow up on, and the inspection would be fine?

15 A. Yes. I can't say it happened
16 often or not often, I don't recall how often it
17 happened. But my recollection is that I don't
18 recall any instances where an issue was not
19 resolved.

20 Q. All right. Go to the next
21 inspection report at store 1225 on 5/19 of '09.
22 And I see compared to the prior inspection
23 report you got different items circled. So on
24 this inspection of this Giant Eagle store, you
25 decided to inspect in certain areas that were

1 different than the one we just looked at,
2 right?

3 A. I'll have to rely on your exhibit
4 because my copy is not legible.

5 MR. THOMAS: Mr. Barnes, can you
6 please give me the Bates number again for this?

7 MR. BARNES: Sure. 2373.

8 MR. THOMAS: 2373.

9 MR. BARNES: 2802373.

10 MR. THOMAS: One moment while I
11 scroll to it.

12 A. I'm sorry. I am able to read that
13 one. It was the one prior to that that I can't
14 read.

15 BY MR. BARNES:

16 Q. Oh, yeah, that was a duplicate of
17 the prior one. It just found its way in there.

18 A. Okay.

19 Q. The next inspection begins on
20 2802373. Do you see that one?

21 A. Yes.

22 Q. And so what I'm just observing is,
23 is that you circle a bunch of items on the left
24 that are slightly different from the prior
25 inspection. Am I correct that's you, as the

1 agent, using your discretion and judgment to
2 say, I'm going to look at these items today,
3 I'm not going to just match what I did the last
4 time, right?

5 A. Correct.

6 Q. All right. And so in this
7 inspection we don't see anything for follow-up.
8 It's called a so-called pink sheet, is that the
9 follow-up sheet?

10 A. Yes. There was no pink sheet
11 issued for this inspection.

12 Q. A pink sheet means follow up on
13 these items within 30 days?

14 A. Correct.

15 Q. All right. Now, in this one you
16 looked at things like accountability, number
17 10, again. And on page 2 of this inspection
18 report you advised Giant Eagle that they're
19 supposed to keep these records for three years.

20 Do you see that? Is that the
21 recordkeeping requirement that you recall for
22 these types of records?

23 A. It must have been at that point.

24 Q. You mentioned -- now here you look
25 at number 13. You didn't look at 13 on the

1 other inspection we looked at, but here you
2 mention perpetual control II inventory
3 maintained in logbook for number 13.

4 Is that a good control, as far as
5 you're concerned, from the Board's perspective
6 to have a perpetual control II inventory?

7 A. Yes.

8 Q. And did you consider this to
9 exceed the Board's requirements for --

10 A. It was not required by us, so
11 someone performing that would be exceeding,
12 yes.

13 Q. Okay. And then you also looked at
14 something new -- well, not new, but you looked
15 at the prescription information. You checked
16 whether Giant Eagle was complying with that
17 requirement and you say, Patient name and
18 address properly documented, phone-in
19 prescriptions properly documented, et cetera.

20 So that's something that you
21 looked at in this inspection, actually how they
22 were issuing their prescriptions and had the
23 proper information, correct?

24 A. Correct.

25 Q. You also looked at their filing

1 system, number 26, and found them to be in
2 compliance, correct?

3 A. Correct.

4 Q. You checked their last biennial
5 inventory and found it to be in compliance in
6 terms of having it available, right?

7 A. Correct.

8 Q. Number 32 you say that daily
9 dispensing authentication log documented all
10 prescriptions that had been verified, new and
11 refill. Log is signed by each daily dispensing
12 pharmacist.

13 Is that in excess of the Board's
14 requirements to do -- to have these kinds of
15 logs?

16 A. No, I believe those were required
17 to be signed. The log and the refill log were
18 required to be maintained and signed.

19 Q. Okay. And then for 37 you looked
20 at the counseling, counseling logbook. You
21 found that to be in compliance?

22 A. Yes.

23 Q. And then 39, you signed them up
24 for OARRS. And is that something that you
25 tried to do in the early days of OARRS, to get

1 people to sign up?

2 A. Yes.

3 Q. They weren't required to sign up,
4 but you recommended it?

5 A. Correct, initially.

6 Q. Okay. Now, these inspection
7 reports, the next one beginning at 1905, you'll
8 see that these are all -- the first three are
9 all full inspections, and this -- yeah,
10 including this one. And you mark in this
11 inspection of our store 216 various items. I
12 see nothing for follow-up on a pink sheet,
13 meaning that this inspection went fine?

14 A. Yes.

15 Q. And you note various things in
16 this inspection, including patient profiles and
17 meeting minimum standards and barricades are
18 fine, using the right software system,
19 accountability, perpetual logs.

20 So, again, a clean inspection by
21 you of this Giant Eagle store in May of '09?

22 A. Yes.

23 Q. Correct?

24 A. Correct.

25 Q. And we can hop, skip, and jump

1 through these. The next one begins on 2599,
2 another full inspection, this time of Giant
3 Eagle Pharmacy 1217 on 7/13 of '09. Was this a
4 good inspection, you have nothing for
5 follow-up?

6 A. Yes.

7 Q. And, again, you used your judgment
8 as to what things you were going to look at on
9 this inspection, correct?

10 A. Correct.

11 Q. And so I don't see anything
12 remarkable in this inspection. They seem to
13 start getting repetitive.

14 Did you find that across the Giant
15 Eagle chain, that they tended to have the same
16 types of software systems and controls?

17 A. Yes.

18 Q. And did those controls generally
19 meet the Board's requirements?

20 A. Yes.

21 Q. In your inspections, did you from
22 time to time review the DUR process?

23 A. From time to time, yes.

24 Q. If you look at the next inspection
25 of Giant Eagle store 0196 beginning on 2801763,

1 is this another clean inspection of a Giant
2 Eagle store by you?

3 A. Yes. There was no written warning
4 there.

5 Q. Again, this is a full inspection
6 where you had discretion to look at anything
7 you wanted?

8 A. Yes.

9 Q. Go to the next inspection
10 beginning on 2331. This is another full
11 inspection prepared by you of Giant Eagle store
12 6377 on September 16th of 2010. Is this
13 another clean inspection of a Giant Eagle
14 store?

15 A. Yes.

16 Q. No follow-up needed.

17 The next inspection is a part of
18 Giant Eagle store 1217 of 11/15 of '10,
19 beginning on page 280573 (sic). Now, here we
20 have two follow-up items, 9 and 11, as written
21 up by you, correct?

22 A. Correct.

23 Q. And so one of the items is
24 improper dispensing. So is this an example of
25 where you actually did look at dispensing

1 practices to see if they complied with Board
2 requirements?

3 A. Yes.

4 Q. All right. And the problem that
5 you found with number 11 on page 2575, you
6 found a specific prescription was dispensed
7 improperly on 10/7 of '10. It was written for
8 Rynatan suspension but was dispensed for
9 Nystatin oral suspension?

10 A. Yes.

11 Q. And you reviewed that incident
12 with Pharmacist Smith. He indicates
13 prescription was entered incorrectly. Although
14 he checked prescription, the error was not
15 identified. Since the error occurred, store
16 has implemented a new workflow system which has
17 imposed -- improved efficiency.

18 Was that something that when you
19 were looking at the dispensing practices of
20 this store, you found this prescription and
21 noted that it was improperly dispensed,
22 correct?

23 A. Either that or we received a
24 complaint from a consumer on that prescription
25 and then went in to check it. So sometimes --

1 sometimes our inspections resulted from a
2 complaint, for instance, an error, and then we
3 would go in and check -- you know, check what
4 the person was telling us and see what
5 happened. So I'm not sure in this case if I
6 identified that during the inspection or if
7 that was something that came into us as a
8 complaint which then prompted the inspection.

9 Q. All right. And on page 2587
10 there's -- the Giant Eagle pharmacist responds,
11 right, explaining what happened with the
12 improper dispensing?

13 Do you see that?

14 A. Yes.

15 Q. 2587?

16 A. Yes.

17 Q. It says, The error occurred at
18 data entry but was missed at data verification.
19 And then it explains the new workflow system
20 including a 7-point check.

21 Was that an adequate resolution of
22 this issue in this inspection?

23 A. I don't -- I don't recall that
24 there was any other follow-up data.

25 Q. Okay. And so that's number 11.

1 You also found an issue with, I guess,
2 refrigeration, number 9?

3 A. Yes.

4 Q. Was that fixed to your
5 satisfaction?

6 A. Yes, I believe so.

7 Q. Go to page 2378, please. This is
8 an inspection of a Giant Eagle store 1225 on
9 2/16 of '11 performed by you; am I correct?

10 A. Yes.

11 MR. APPEL: One quick question,
12 since you're at a natural breaking point, when
13 do you want to take lunch?

14 MR. BARNES: 12:30. Is that okay?

15 MR. APPEL: That will work.

16 MR. BARNES: Okay. How about you,
17 Mr. Edwards, can you go to 12:30?

18 THE WITNESS: Yep.

19 MR. BARNES: All right. Thank
20 you.

21 BY MR. BARNES:

22 Q. Is this a clean inspection of a
23 Giant Eagle Pharmacy 1225 in February of 2011?

24 A. I believe, yes, it appears so.
25 There was no written warning.

1 Q. There's a reference on page 1 to
2 the DUR verification. The DUR verification
3 patient profile searches --

4 MR. THOMAS: Hold on, Mr. Barnes.
5 I don't seem to have 2378. It might be -- the
6 Bates number might be out of order with the
7 rest of the document.

8 MR. BARNES: Okay. Can you --

9 THE WITNESS: Yes, it comes after
10 2588.

11 MR. BARNES: It's probably about 16
12 or 18 pages into the exhibit. Did you find it?

13 MR. THOMAS: I'm looking.

14 MR. BARNES: 2378.

15 MR. THOMAS: It's a big exhibit.
16 One sec.

17 MR. BARNES: While you're looking,
18 we have hard copies.

19 BY MR. BARNES:

20 Q. I just have a few questions about
21 this inspection, Mr. Edwards.

22 A. Yes.

23 Q. There's a reference to the DUR
24 verification system on page 1. Does that
25 reflect that part of this inspection, you

1 reviewed the adequacy of the record system,
2 including DUR verification?

3 A. That tells me that their system
4 was capable of doing those things. I don't
5 know that I specifically went in and checked
6 prescriptions to make sure there was DUR done,
7 but it's telling me that that software is
8 capable of doing those things.

9 Q. Okay. But if you wanted to check,
10 you had free access to check that, correct?

11 A. Correct.

12 Q. All right. The next inspection is
13 on 4/1 of '11 on page 2339. This appears to be
14 a unremarkable partial inspection; is that
15 right?

16 A. Yes. That was, yeah, for a
17 remodel.

18 Q. And you checked the barricade
19 system and everything was fine?

20 A. Yes.

21 Q. The next inspection is on page
22 1915. This is store number 216. And you had
23 an issue with item 29, which is DEA inventory.
24 And that's referenced on page 1919. You
25 couldn't find it, you asked for it, and you

1 issued a pink copy saying you better find it,
2 essentially, correct?

3 A. Correct.

4 Q. And was that resolved to your
5 satisfaction?

6 A. It looks like --

7 Q. If you look at page 1913.

8 A. Yeah, it looks like I had to come
9 back for another issue maybe or --

10 Q. Okay. And did you get your
11 inventory that you noted that you couldn't find
12 the prior time you were there on 4/14?

13 A. I don't know. I don't see -- is
14 there an exhibit that's the response? I don't
15 see it.

16 Q. You say on 1913, a completed
17 control -- a complete controlled substance
18 inventory must be completed as soon as
19 possible.

20 A. Yes. So I don't think it was
21 located. I think I went back in and told them
22 that they had to complete a new one.

23 Q. Okay. Do you believe that that
24 was done?

25 A. I don't recall because I don't see

1 the document here. I'm not sure.

2 Q. Okay. Other than not being able
3 to find a copy of the last inventory, was this
4 otherwise a good inspection?

5 A. Yes. That was the only item
6 noted.

7 Q. The next inspection that you did
8 on page 2343 was Giant Eagle store 6377. This
9 looks like a partial barricade inspection,
10 barricade approved?

11 A. Yes.

12 Q. Unremarkable inspection. I mean,
13 other than that issue.

14 The next inspection is on 8177,
15 store number 196. This looks like a copy of
16 what we just saw. Or no, it's not a copy.

17 A. It's a different one.

18 Q. A different one. Here again,
19 clean inspection other than you couldn't find
20 the DEA inventory?

21 A. No. It says it was a partial.
22 They did accounting for the schedule II meds
23 but III through V medications were not included
24 in the inventory, so I instructed them to
25 complete an inventory with all controls.

1 Q. Did they do -- did they do so, as
2 far as you remember?

3 A. I don't recall. I don't see the
4 response in here, so I can't answer that.

5 Q. Well, if they didn't comply with
6 the pink sheet, there would have been
7 repercussions, correct?

8 A. There should have been, yes.

9 Q. Okay. I don't know it's in the
10 records.

11 A. Like with the previous inspection,
12 I would -- if they didn't comply, I would have
13 gone back in and ensured compliance.

14 Q. All right. The next inspection
15 begins on 2347?

16 A. Yes.

17 Q. Store 196 in Painesville, Ohio.
18 And you have two follow-up items: improper
19 dispensing and prescription files. Now, for
20 that item, number 10, actually -- you don't
21 have number 10 as a follow-up, but on page 2
22 you reference that in the records that you
23 requested and were given, you saw some McKesson
24 invoices that said monthly regulatory maximum
25 purchases exceeded. You didn't see any -- you

1 hadn't seen such a report before?

2 A. Correct.

3 Q. Did you ask for any follow-up on
4 that?

5 A. I don't recall.

6 Q. Okay. For improper dispensing on
7 page 3 you note that a certain prescription was
8 filled for furosemide?

9 A. Furosemide.

10 Q. Furosemide. And then it was
11 refilled three days later, filled too early.
12 You say, unacceptable for a technician to
13 bypass DUR warning without informing the
14 pharmacist.

15 So there you found an instance
16 where a tech had overridden the DUR and you're
17 telling the Giant Eagle store, don't allow that
18 to happen?

19 A. Right.

20 Q. And there's a response on page
21 2357. Was that a satisfactory response as far
22 as you were concerned?

23 A. I believe so.

24 Q. Okay. And then apparently, item
25 number 26, you wanted follow-up because you

1 couldn't find a hard copy of the prescription,
2 and Giant Eagle's response was it was found
3 after the prescription and misfiled and they
4 enclosed a copy of it. So was that a
5 satisfactory response?

6 A. Yes.

7 Q. Page 9864 is another inspection,
8 this time in Trumbull County. It looks like --
9 I can't tell if it's full or partial. Can you
10 tell us what the nature and purpose of this
11 inspection was?

12 A. Looks like I was conducting an
13 investigation and I was requesting hard copy
14 prescriptions and signature logs to aid in the
15 investigation.

16 Q. So you went to the store and you
17 recorded the fact that you were taking these
18 records out of the store?

19 A. Correct.

20 Q. All right. This was an
21 investigation that had something to do with
22 some other individuals or entities?

23 A. Right.

24 Q. Okay. And then the last one we'll
25 cover before lunch is the next one, 2589. This

1 is an inspection on 2/5 of '13, a store number
2 1217. This was a clean inspection, correct?

3 A. Yes. It looks so.

4 Q. You again mention the DUR
5 verification process on the first page. It
6 says, DUR verification daily dispensing
7 authentication log printout signed by
8 dispensing pharmacist. Daily cognitive
9 services report lists all prescriptions with
10 DUR issues and pharmacist who resolved the
11 issue.

12 Was that satisfactory from the
13 Board's perspective, that system that Giant
14 Eagle had?

15 A. Right. It was me documenting that
16 the pharmacy had that system, which was capable
17 of doing those things.

18 Q. And then you mention on page 3,
19 controlled substance II files checked,
20 prescriptions properly contain prescriber, DEA,
21 quantity, et cetera. So Giant Eagle was
22 meeting the prescription information
23 requirement; is that right?

24 A. On the prescriptions I checked,
25 yes.

1 Q. Okay. And you spot checked, you
2 randomly selected these prescriptions?

3 A. Correct.

4 Q. You didn't tell Giant Eagle in
5 advance, I'm going to come in and check these
6 prescriptions?

7 A. No.

8 Q. You just somehow select them
9 randomly and said, I want to see this one, this
10 one, this one, and this one?

11 A. Correct, I'll like go in their
12 files and just pick out an envelope or a
13 California folder and look in the scripts in
14 their folder.

15 Q. And then the next page, 2595,
16 number 32, you reference the daily
17 authentication log signed by the dispensing
18 pharmacist. Log lists all new and refill
19 prescriptions.

20 So is that a good control and did
21 it meet the Board's requirements to have a
22 daily authentication log signed by each
23 dispensing pharmacist?

24 A. Yes.

25 MR. BARNES: All right. We'll take,

1 I guess, an hour-long lunch break. We'll
2 reconvene at approximately 1:30.

3 THE WITNESS: Okay.

4 MR. BARNES: All right. Thank you.

5 THE VIDEOGRAPHER: Off the record at
6 12:31.

7 (Off the record.)

8 THE VIDEOGRAPHER: On the record
9 1:30.

10 BY MR. BARNES:

11 Q. All right. Good afternoon,
12 Mr. Edwards. We're resuming your deposition
13 after a lunch break. We were going through
14 your inspection reports, and I want to finish
15 that process beginning on page 2383 of
16 Exhibit -- I believe it's 13. I'm sorry. 15.

17 It's an -- they're in chronological
18 order. This is an inspection dated October 30th
19 of 2013 of Giant Eagle store number 1225.

20 A. I see it.

21 Q. And I see there's no follow-up
22 items. So is this another example of a clean
23 inspection --

24 A. Yes.

25 Q. -- of a Giant Eagle Pharmacy? On

1 page 1 of -- on page 1 of this inspection,
2 there's a reference to that this pharmacy began
3 using a new dispensing system, a McKesson PDX
4 enterprise dispensing system in July of '13.
5 DUR issues may only be resolved by pharmacists.
6 New system has biometric fingerprint scanner
7 used in final act of verification. System
8 gives a warning tone when techs or pharmacists
9 scan incorrectly or when too much time has
10 lapsed during the fill process. Data is backed
11 up at corporate. Giant Eagle stores are all
12 connected for patient profiling.

13 Did you view that as a good system
14 indicative of good internal controls at this
15 Giant Eagle Pharmacy?

16 A. Yes.

17 Q. The reference to DUR, were you
18 happy that only the pharmacists under this
19 system could resolve DUR issues?

20 A. Yes. That was an improvement.

21 Q. Okay. And did you find that type
22 of system in the other Giant Eagle stores after
23 this time period, in other --

24 A. I believe it was a gradual
25 rollout. It wasn't all the stores all at once.

1 It was a year, maybe year-plus rollout.

2 Q. Okay. Go to the next inspection
3 document, 2271.

4 A. Yes.

5 Q. Store number 6377. Now, this
6 is -- has a lot of writing and it actually
7 required a follow-up, which is on page 2283.
8 So this inspection shows that you wanted
9 follow-ups on 27, 28, and 11. And according to
10 the Giant Eagle response on 2283, apparently
11 there was an issue that you spotted in your
12 inspection with a certain prescription being
13 filled on 11/26 of '13. It was written for 90
14 capsules, however, complainant states that the
15 prescription was dispensed for 130. Pharmacist
16 believes the quantity may have been
17 back-counted from a 150-count bottle.

18 That was something that you tested
19 at least one of the prescriptions and you
20 wanted follow-up because apparently you had
21 received a complaint of a differential between
22 90 and 130?

23 A. Yes, that's what it looks like. I
24 think the majority of this inspection was
25 completed by Lisa Dietsche at this level, and

1 then I documented the item 11.

2 Q. Okay. And was that satisfied by
3 Giant Eagle to your satisfaction?

4 A. I believe so. I see the response
5 here.

6 Q. Okay. And then you also wanted a
7 response to 27 and 28. 27 was a transfer
8 prescription, and then for 28 there was a
9 problem with samples of controlled IIs do not
10 have INT date on hard copy originals. You
11 wanted that to be on the hard copy originals?

12 A. Yeah, looks like it.

13 Q. Okay. And did Giant Eagle
14 satisfactorily fix that for you?

15 A. I believe so.

16 Q. Okay. And then the next
17 inspection is 5/7 of '14 on Bates 1923. This
18 looks like a clean inspection, nothing to
19 follow up, everything was fine at store 216 on
20 this date, according to this full inspection
21 that you conducted?

22 A. Right.

23 Q. I don't see anything remarkable in
24 there.

25 Next inspection was on 7/7 of '14,

1 store number 4097. Nothing to follow up, clean
2 inspection. Is that accurate?

3 A. Yes.

4 Q. Then the next inspection was on
5 1/7 of '15 store number 196, another clean
6 inspection by you of that store, no problems
7 noted. You list certain controls, perpetual
8 inventory logs, things of that nature. This
9 store satisfied your inspection at that point
10 in time?

11 A. Yes.

12 Q. Now we have -- the next document
13 beginning at 2639, we have an inspection of
14 store 1217 on August 10, 2015. Does this kind
15 of refresh your recollection of when you went
16 digital?

17 A. Yes. Sometime around that time.

18 Q. All right. And so there's now a
19 new format for this inspection and it looks
20 like things aren't circled, you just provide
21 answers to all the questions now; is that
22 right?

23 A. Correct. There's like drop-down
24 boxes for answering most of the questions.
25 There are some areas to enter in text, but

1 there's a lot of drop-down.

2 Q. This inspection, if you go to page
3 5 of 11 on Bates 2643, you appear at the top of
4 page 5 to be evaluating Giant Eagle's software
5 system dispensing terminals, and this part of
6 the inspection looked at DUR and verification
7 when it was done. Does the pharmacy's realtime
8 ARKS prevent the patient from receiving more
9 dispensing than authorized by the original
10 prescription? And you answered yes.

11 Is that something that you covered
12 in the inspection and were satisfied that Giant
13 Eagle's systems prevented more dispensing than
14 what was authorized?

15 A. Yes.

16 Q. What is the ARKS system?

17 A. Alternate recordkeeping system.

18 Q. Okay. And then the rest of page 5
19 list what appear to be attributes of this
20 system. Is it -- are the required records of
21 accountability being kept, are there audit
22 trails, is there proper security, and you
23 answered all of those in the affirmative, that
24 all of this met your requirements?

25 A. Correct.

1 Q. On the next page under number 5,
2 minimum standards, number 7 under number 5, Is
3 there evidence to indicate a problem with
4 staffing levels? And you said no.

5 Is that something that you
6 evaluated at the stores when you did your
7 inspections, were they adequately staffed with
8 respect to pharmacists and techs and employees?

9 A. That's generally a question that
10 we would ask the pharmacist or --

11 Q. Okay.

12 A. -- or if we observe, you know,
13 something like the place is totally chaotic and
14 things are out of control, then, I mean, it
15 would be based on a firsthand observation.

16 Q. I see. In your experience as an
17 agent, did you from time to time observe things
18 going on in, you know, some pharmacies, you
19 know, that would be indicative to you that
20 there might be a problem of maybe diversion,
21 like maybe long lines out the door, people
22 waiting for it to be opened, you know, things
23 of that nature?

24 A. Not in the pharmacies that I was
25 inspecting, that I recall.

1 Q. Okay. On page 7 of 11 on document
2 2645, number 11, Improper Dispensing. Are the
3 pharmacists performing a prospective drug
4 utilization review? Answer: Yes. Is the
5 pharmacy using the correct NDC number when
6 dispensing drugs? No.

7 Let's look at the first one. In
8 this inspection you checked to see whether the
9 pharmacists were doing a prospective DUR?

10 A. Yes.

11 Q. And what does the no answer mean
12 under below, Is the pharmacy using the correct
13 NDC number when dispensing drugs? Is that a
14 follow-up item that you wanted?

15 A. I don't see that it was marked --
16 well, it says written response required. But
17 that was -- that was for number 19, not number
18 11. I don't know if that was a typo or if
19 that -- I'm not sure.

20 Q. Okay. Where are you looking for
21 the written response required, what page?

22 A. Well, I was just flipping through,
23 and I don't see one.

24 Q. Okay. Number 12 is Insufficient
25 Supervision. You answered yes to both

1 questions. Is there a pharmacist supervision
2 of the dangerous drugs and other pharmacy
3 employees at all times while the pharmacy's
4 open and operating? Yes. Are only pharmacists
5 performing tasks requiring professional
6 judgment? Answer: Yes.

7 That was something that you
8 covered in this inspection and were satisfied
9 with the evidence that that was being met?

10 A. Yes.

11 Q. And number 13 is Inventory
12 Records, and you answer yes to both. You
13 mention the perpetual C-II log. So Giant
14 Eagle's inventory controls in this inspection
15 were fine?

16 A. Yes.

17 Q. On the next page under 18.1, DUR
18 Software. Does the pharmacist rely solely on
19 the dispensing software to perform the DUR for
20 prescription dispensing? And you answered no.

21 So as part of this inspection, you
22 looked into whether or not the pharmacists were
23 simply following the software or doing
24 something more that was required?

25 A. Yeah, I don't know if I physically

1 observed them completing DUR on a prescription
2 or simply asked them if they only rely on the
3 software. I'm not sure how I approached that
4 question. But I see that now.

5 Q. All right. And number 19, there
6 was an error in dispensing. And you wanted a
7 response in writing?

8 A. Correct.

9 Q. It looks like you got a response
10 in writing to your satisfaction?

11 A. I believe so. Right. Well, I
12 don't know. I don't see the response here. So
13 I guess I can't really answer that because I
14 don't see the response included in here.

15 Q. Well, this says under 19,
16 Corrective Action, Action plan began on 7/30/15
17 with intervention of pharmacy district manager.
18 So --

19 A. Maybe that was already in the
20 works prior to my inspection, maybe. I don't
21 know.

22 Q. Okay.

23 A. I don't recall.

24 Q. All right. And then the rest of
25 the inspection deals with drug labels and

1 signatures and refills and things of that
2 nature. This inspection following the one
3 follow-up you asked for, was this a clean
4 inspection of this store at this time?

5 A. It appears so.

6 Q. We have a similar looking
7 inspection report next at 6695. This is store
8 number 196 on 10/15 of '15. And we see similar
9 format as the last one. But this time you
10 asked for some follow-up. On the second page,
11 you wanted follow-up concerning an improper
12 dispensing, DUR software, OARRS, and records.

13 Giant Eagle provided a response
14 on -- it's after page 6704.

15 A. Yes, I see that.

16 Q. So is this an example where you
17 looked at the details of pharmacists following
18 the DUR and you wanted follow-up information
19 regarding that?

20 A. Yes. I don't recall if it's
21 something I observed in the pharmacy or if it
22 was based on a complaint that we received that
23 I followed up on.

24 Q. If you look on page 8 of 11, Bates
25 stamped 6702, it looks like the matter related

1 to a prescription being filled for a total
2 quantity of 21 tablets using two different
3 NDCs. Pharmacist received a DUR warning for
4 therapeutic duplication and completed a DUR
5 override without taking any documented steps to
6 resolve the issue. Neither the prescribers
7 were called, an OARRS report was not run.

8 But then in the response on
9 number 11, he provides a response. Said, The
10 patient in question had been receiving
11 prescriptions at this location for over a year.
12 This was a short-term increase. Based on the
13 patient's past dispensing history for multiple
14 medical conditions, I did not suspect a pattern
15 of abuse. Was paid for by a third-party
16 carrier which wasn't rejected. Going forward,
17 I will make a more concerted effort to more
18 thoroughly investigate.

19 Were you satisfied with that
20 response?

21 A. Well, I'm now remembering this
22 incident, and that -- I believe that pharmacist
23 was either not even signed up for OARRS or
24 never ran OARRS reports. So that was -- that
25 was kind of a big deal. I don't know -- I

1 don't know that I was satisfied. I seem to
2 recall possibly there was maybe a hearing
3 involving this pharmacist or -- I don't recall
4 specifically, but I think there might have been
5 additional action taken against this
6 pharmacist.

7 Q. You don't recall that specifically
8 one way or the other?

9 A. In my mind, I remember him not
10 ever running OARRS reports, and I feel like it
11 was escalated beyond the inspection, but I
12 can't say for sure.

13 Q. Okay. But -- all right. You
14 don't know one way or the other. You would
15 have to look at more documents?

16 A. Correct.

17 Q. But in any event, did this
18 inspection -- were all of the issues resolved
19 to your satisfaction?

20 A. Yes, the issues unrelated to
21 Mr. Heppner, the other issues of the pharmacy
22 were resolved.

23 Q. Okay. Now, the report beginning
24 on 6739 appears to just be a short report. You
25 requested records from this pharmacy, and they

1 provided them to you?

2 A. What page number are you on?

3 Q. I am on 6705. This appears to be
4 a follow-up report to the prior inspection.
5 It's dated the same date.

6 A. Okay. Yeah.

7 Q. Same pharmacy.

8 A. Yes.

9 Q. So this appears to be a follow-up.
10 And requested records. You wanted dispensing
11 data for all controlled substances filled at
12 this pharmacy between 8/1 of '15 and 10/14 of
13 '15. Were those records provided to you?

14 A. I believe so, yes.

15 Q. And the next page says, Written
16 Response Required Details. Does the pharmacist
17 have access to OARRS to request reports when
18 needed?

19 And you made an observation,
20 Corrective Action, Giant Eagle must correct
21 their software to ensure that individual
22 prescriptions filled with multiple NDC numbers
23 are properly reported to the OARRS database,
24 and you cite the statutes. So that was the
25 resolution of that inspection?

1 A. I believe so.

2 Q. And the last item is just a
3 property receipt on document 6578 for a store
4 in Trumbull County, Warren, Ohio. You took
5 original prescriptions probably in connection
6 with an investigation; is that right?

7 A. Yes. That's correct.

8 Q. All right. Mr. Edwards, we've now
9 did a march through all of your inspections. I
10 think there were approximately 26 inspections.
11 And we saw from time to time that in certain
12 inspections you required follow-up, you wanted
13 Giant Eagle to improve their procedures, you
14 know, you had various recommendations.

15 In general, though, did Giant
16 Eagle always cooperate with you and follow your
17 recommendations?

18 A. I believe so, for the most part,
19 yes.

20 Q. Is it a fair statement that at all
21 times in which you were involved inspecting the
22 Giant Eagle stores in Lake and Trumbull County
23 that Giant Eagle met the requirements for the
24 licenses for their stores and for the renewal
25 of their licenses at all times?

1 A. I believe so. I don't recall an
2 instance where that wasn't the case.

3 Q. No license was ever suspended or
4 revoked by the Board for any Giant Eagle
5 pharmacy, as far as you know?

6 A. As far as I know, no.

7 Q. Did the Giant Eagle Pharmacies
8 comply with the Ohio security requirements at
9 all times?

10 A. As far as I know.

11 Q. Did Giant Eagle stores, in fact,
12 have in some instances more or better controls
13 than were required by the Board?

14 A. Yes.

15 Q. Is it true that Giant Eagle was
16 never cited or disciplined by the Board for
17 failing to meet any of their requirements?

18 A. You're speaking specifically to
19 Lake and Trumbull?

20 Q. Yes.

21 A. To my knowledge, no, they were
22 not.

23 Q. We talked about staffing before.
24 From your involvement with the inspections,
25 were the Giant Eagle pharmacists educated,

1 hard-working pharmacists who were attempting to
2 do the best job they could?

3 A. As far as I could tell.

4 Q. Did they adequately train and
5 supervise pharmacy techs and others working in
6 the pharmacy?

7 A. If I could back up saying with the
8 exception of Mr. Heppner, the fact that --

9 THE REPORTER: You're trailing
10 off. I can't hear you. Please repeat.

11 THE WITNESS: Sorry.

12 A. I said, with the exception of
13 Mr. Heppner, that's the only pharmacist I could
14 recall who didn't meet -- didn't meet our
15 standards and was --

16 BY MR. BARNES:

17 Q. Was disciplinary action taken
18 against him?

19 A. I don't recall if -- again, I
20 would need to see more documents to see if
21 there was a citation issued or requested.

22 Q. Okay. Is it a fair statement that
23 Giant Eagle Pharmacies complied with the manner
24 of processing prescription requirements
25 including performing drug utilization reviews

1 at all times?

2 A. At all times that I'm aware.

3 Q. Okay. In any of your inspections,
4 the 26 that you did, did you ever see any
5 evidence that Giant Eagle Pharmacies were
6 filling illegitimate opioid prescriptions?

7 A. No --

8 MR. CIACCIO: Objection to form.

9 A. -- not that I --

10 THE REPORTER: Is that Joe? I'm
11 sorry. Is that Joe?

12 MR. CIACCIO: Yes. I'm sorry.
13 Joe Ciaccio.

14 THE REPORTER: Thank you.

15 MR. BARNES: Did you get his
16 answer, Patti?

17 THE REPORTER: Yes.

18 MR. BARNES: Thank you.

19 BY MR. BARNES:

20 Q. At any time when you were at the
21 Lake County Narcotics Agency or at the Ohio
22 Board since 2008, to your knowledge, were Giant
23 Eagle Pharmacies ever the subject of criminal
24 investigations or investigations related to
25 diversionary behavior in the pharmacies?

1 A. You're talking about the pharmacy
2 itself, or are you talking about the employees
3 of the pharmacy?

4 Q. Let's start with the pharmacy
5 itself. Pharmacies.

6 A. No, not to my knowledge. The
7 actual pharmacy itself, we did not take
8 disciplinary action against the terminal
9 distributor, to my knowledge.

10 Q. Yeah. Okay. My question was a
11 little different. In your years with the LCNA
12 and now with the Board, was Giant Eagle ever
13 the subject of criminal or civil investigation
14 because of alleged diversion of controlled
15 substances?

16 A. You're referring to Giant Eagle,
17 the corporation itself?

18 Q. Yes.

19 A. No.

20 Q. Okay. As far as you're concerned,
21 Mr. Edwards, were the Giant Eagle Pharmacies
22 that you inspected over the years 2009 to 2019
23 in Lake and Trumbull Counties, were those
24 pharmacies operating lawfully at all times?

25 A. As far as I knew.

1 Q. As far as you knew, Mr. Edwards,
2 from 2009 through 2000 (sic), your time with
3 the Board, were the Giant Eagle Pharmacies
4 operating in a manner that was contributing in
5 any way to the diversion of prescription
6 opioids in Lake or Trumbull Counties?

7 A. Not as far as I knew.

8 Q. Did you ever see any evidence that
9 Giant Eagle or its pharmacists were knowingly
10 filling prescriptions that were invalid or not
11 for a legitimate medical purpose?

12 A. Not that I recall.

13 Q. Were Giant Eagle and its
14 pharmacists actively assisting law enforcement
15 with anti-diversion efforts from the time you
16 started at LCNA until now?

17 A. Yes. With me, yes.

18 Q. With respect to the other pharmacy
19 defendants, CVS, Rite-Aid, Walmart, and
20 Walgreens, would your answers be the same with
21 respect to those defendants, their stores
22 meeting the security requirement imposed by the
23 Board of Pharmacy?

24 MR. CIACCIO: Objection. Form. Joe.

25 A. I don't recall any instances where

1 pharmacies were disciplined for not meeting
2 those standards.

3 BY MR. BARNES:

4 Q. Okay. And by the other pharmacy
5 defendants, I mean CVS, Rite-Aid, Walmart, and
6 Walgreens. Were those entities adequately
7 staffed as far as you could tell from your
8 inspections?

9 A. As far as I could tell through my
10 inspections.

11 Q. And were those pharmacies also
12 complying with the manner of processing
13 prescription requirements imposed by the Ohio
14 regulations, as far as you knew?

15 A. As far as I knew. I mean, it's
16 difficult to answer a blanket yes without
17 seeing examples of past inspections and, you
18 know, doing a more thorough search like we did
19 with the Giant Eagle stuff, but nothing comes
20 to mind that --

21 Q. And were these other pharmacies
22 operating lawfully, as far as you knew?

23 A. As far as I knew.

24 Q. And were these other pharmacies
25 operating in any manner that was contributing

1 to the diversion of prescription opioids into
2 Lake and Trumbull Counties?

3 MR. CIACCIO: Objection. Form.

4 BY MR. BARNES:

5 Q. I'm sorry, sir. What was your
6 answer?

7 A. Not that I recall.

8 Q. Were pharmacists at any of these
9 other pharmacies knowingly filling
10 prescriptions that were invalid or not for a
11 legitimate medical purpose, as far as you knew?

12 A. Not that I know of.

13 Q. Were these other pharmacies
14 assisting you in law enforcement with
15 anti-diversion efforts in Lake and Trumbull
16 Counties?

17 A. Yes, I believe so.

18 Q. I want to turn your attention,
19 Mr. Edwards, to diversion in general. Are you
20 familiar with Internet pharmacies?

21 A. Yes.

22 Q. Was there a period of time in
23 which Internet pharmacies were operating in or
24 around Lake and Trumbull County dispensing into
25 or out of the counties?

1 A. I believe they were dispensing
2 everywhere, but I don't -- I didn't -- I don't
3 have any specific recollection of cases that I
4 worked on involving an Internet pharmacy.

5 Q. Do you know them -- the Internet
6 pharmacies to have been a significant source of
7 diversion of controlled substances?

8 A. When you say Internet pharmacy,
9 are you referring to a properly licensed entity
10 or -- because when I think of Internet
11 pharmacy, I think of, you know -- I mean, that
12 could mean anything. It could mean something
13 legitimate or it could mean, you know, getting
14 prescription drugs from another country over
15 the Internet. So when you say Internet
16 pharmacy, what do you mean?

17 Q. What I mean is a pharmacy that
18 advertised on the Internet and filled
19 prescriptions over the Internet.

20 A. Licensed or unlicensed?

21 Q. Yes.

22 A. I recall instances of those, but
23 not -- what was your specific question?

24 Q. My specific question was, in
25 your -- both of your jobs at LCNA or at the

1 Board, was there a period of time in which you
2 were aware that Internet pharmacies were
3 operating and filling controlled substances,
4 prescriptions that were finding their way into
5 Lake and Trumbull Counties?

6 A. Generally speaking, yes, I
7 remember being aware of them, but I don't have
8 specific recollections of specific pharmacies
9 or patients or any detail.

10 Q. Okay. Independent pharmacies
11 operating in Lake and Trumbull County, are you
12 familiar with certain independent pharmacies in
13 both of those counties?

14 A. Mainly Trumbull. There were very
15 few in Lake County, if any. They're all closed
16 now.

17 Q. Okay. Were some of the
18 independent pharmacies major sources of
19 diversion of controlled substances, in your
20 experience?

21 A. I remember there being issues with
22 Overholt's Pharmacy in Trumbull County.

23 Q. Okay. In your experience, the
24 independent pharmacies, did they tend to have
25 weaker or lesser controls than the chain

1 pharmacies?

2 MR. CIACCIO: Objection. Form.

3 A. Generally speaking, I would say
4 yes.

5 BY MR. BARNES:

6 Q. Okay. What about pain clinics,
7 are you familiar with pain clinics operating in
8 Lake and Trumbull Counties?

9 A. Yes.

10 Q. And do you recall any specifically
11 by name?

12 A. Yes.

13 Q. Can you tell us those names?

14 A. Great Lakes Pain Management is
15 one.

16 Q. Where was that located?

17 A. Willoughby Hills.

18 Q. All right. Any others?

19 A. I don't -- I mean, I can recall
20 doctor names, not so much -- not so much their
21 business names.

22 Q. Which doctor names do you
23 remember?

24 A. I recall David Demangone was in
25 Willoughby. I recall Larry Gray; I think it

1 was Pain and Functional Medicine was the name
2 of his business in -- also in Willoughby. I'm
3 trying to think. There were -- well, there
4 were a couple affiliated with Lake Hospital
5 system that I don't recall the names of
6 exactly.

7 Q. Okay. Were these pain clinics,
8 did they tend to prescribe large amounts of
9 controlled substances, including opioids?

10 A. Yes, by the nature of their
11 business.

12 Q. For that reason, were they ever a
13 subject of concern by LCNA or the Ohio Board of
14 Pharmacy?

15 A. For that reason alone?

16 Q. Yes.

17 A. No. I mean --

18 Q. All right. For what other
19 reasons, if any, did they become --

20 A. If you meant -- had you said like
21 a specific incident like a case or a diversion
22 incident, then maybe that would have triggered
23 something, but just the fact that they were
24 pain management clinics did not, you know,
25 automatically make them suspect.

1 Q. Did you inspect pain management
2 clinics ever?

3 A. I did.

4 Q. Did you find them to have weaker
5 or lesser controls than chain pharmacies?

6 A. I wouldn't say weaker or lesser.
7 I wouldn't -- I wouldn't say weaker or lesser.

8 Q. Okay. What about pill mills? Are
9 you familiar with the term pill mill?

10 A. I'm sorry. I said weaker or
11 lesser. I meant weaker or better.

12 Q. Okay. What about -- go ahead.
13 (Reporter interrupted.)

14 A. He said pill mills, I said yes,
15 I'm familiar with the term.

16 BY MR. BARNES:

17 Q. What do you understand a pill mill
18 to be?

19 A. A pill mill is a -- usually a
20 doctor's office that it is not following the
21 standards in terms of prescribing and tends to
22 give out much more medication than what is
23 needed and to people who really shouldn't be
24 getting that medication, quantities that are in
25 excess of normal standards, maybe not good

1 recordkeeping. There's a number of factors.

2 Q. Did you ever inspect any pill
3 mills in Lake or Trumbull Counties?

4 A. I don't believe I ever inspected
5 any.

6 Q. Did you investigate any pill mills
7 in those two counties?

8 A. I did some -- I assisted in some
9 investigations in the Youngstown area. I don't
10 recall if they were Trumbull or Mahoning or
11 where, but I don't -- I don't recall any pill
12 mill doctor investigations in Lake County.

13 Q. Okay. What I'm getting at is,
14 using your definition of pill mills from 2006
15 to 2019, were there pill mills operating in
16 Lake and/or Trumbull Counties?

17 A. Not that I -- not that I recall
18 specifically, not that I personally
19 investigated.

20 Q. Okay. Were you -- as an agent
21 with LCNA and then now with the Board of
22 Pharmacy, were you able to determine whether or
23 not controlled substances were coming into Lake
24 and Trumbull County from other sources like
25 Detroit or Pittsburgh or anywhere outside the

1 state or these two counties?

2 A. I recall a case I had
3 prescriptions were being filled in Florida and
4 being brought back here, but I don't recall the
5 county. I don't recall what county that was
6 in. May have been several.

7 Q. Did you -- in your experience in
8 law enforcement, is it -- looking at a
9 pharmacist -- or a pharmacy's amount of
10 controlled substance dispensing versus their
11 overall dispensing, is that something that you
12 looked or cared about; in other words, if a
13 pharmacy was -- you know, 90 percent of
14 everything they filled was OxyContin versus a
15 normally operating pharmacy, is that a criteria
16 that you considered ever?

17 MR. CIACCIO: Objection. Form.

18 A. It could be. But then there -- I
19 mean, it could be something to look into
20 further because there could be a reasonable
21 explanation, such as it's right next door to a
22 hospital or, you know, it's in the same
23 building as a pain management doctor and it's a
24 small town. I mean, there could be -- it could
25 be a red flag or it could be a legitimate --

1 you know, a legitimate reason.

2 Q. But are you familiar with or did
3 you have any expectations with what a regular
4 pharmacy operating in the normal course of
5 business, what your expectations were with
6 respect to what percentage of their
7 prescriptions were controlled substances?

8 A. No.

9 Q. And have you ever heard of whether
10 the DEA had certain measurements or, you know,
11 yardsticks to say, you know, if you're beyond a
12 certain percentage, there's a cause for
13 concern?

14 A. No, I don't know of any of those
15 figures.

16 Q. I want to direct your attention to
17 Dr. Franklin and the Overholt Pharmacy.

18 A. Yes.

19 Q. That was a rather notorious
20 investigation in Trumbull County, wasn't it,
21 both of those, Dr. Franklin and Overholt
22 Pharmacy?

23 A. I believe that was Geauga County.
24 His office was in Middlefield, I believe. And
25 then Trumbull was where the pharmacy was.

1 Q. Oh, I see. And what was your
2 involvement in the Franklin/Overholt
3 investigation?

4 A. I -- that was right at the time
5 that I switched from LCNA to the Board of
6 Pharmacy. So I started working on it when I
7 was at the Board of Pharmacy, I believe --
8 either I had an informant or some patients in
9 Lake County who were going to Dr. Franklin, and
10 I was working on the case with George Pavlich,
11 who was the Pharmacy Board agent.

12 Q. Is Exhibit 18 a record of your
13 initial involvement with the Franklin Overholt
14 investigation?

15 A. Yes.

16 Q. So this would indicate that in
17 about June of 2008, at the time you were with
18 LCNA still, Pharmacy Diversion Unit?

19 A. Right.

20 Q. You were called in to assist the
21 Board of Pharmacy in their investigation of
22 Dr. Peter S. Franklin?

23 A. Yes.

24 Q. Is that right? And according to
25 this record, one of the first things you did

1 was send in an undercover agent, or a CI, a
2 confidential informant?

3 A. Correct.

4 Q. And what happened? Can you
5 generally tell us how your investigation
6 proceeded from here? You sent in the CI, and
7 then how did things roll out from there?

8 A. Honestly, I do not recall the
9 specifics of the case. It was a very complex
10 case with a lot -- there were multiple
11 informants, I believe.

12 Q. What do you recall the general
13 nature of what was discovered in this
14 investigation? What was -- what were they
15 doing?

16 A. Sure. The general nature was that
17 he was, as you said, a pill mill, and he was
18 prescribing to people outside the legitimate
19 course of medical practice. And an
20 investigation was started, and basically he
21 was -- a search warrant was conducted and he
22 was charged criminally with providing
23 prescriptions to a lot of people who shouldn't
24 otherwise have been receiving those
25 prescriptions.

1 Q. Is Exhibit 19 the search warrant
2 that you just referred to?

3 A. Yes.

4 Q. You're listed on the first
5 paragraph special agent Trey Edwards, Lake
6 County Narcotics Agency.

7 A. Correct.

8 Q. Did you assist in the preparation
9 of the search warrant, including providing
10 information that's listed in the search
11 warrant?

12 A. I'm sure I worked with George
13 Pavlich on preparing this and providing him
14 information, but I don't recall exactly what I
15 gave him or what, if anything, I typed up or he
16 typed up. I don't -- I don't recall writing it
17 myself. I think -- I think this was written by
18 someone else.

19 Q. You're mentioned on page 5736 and
20 there's a synopsis underneath your name of
21 information. Does that refresh your
22 recollection that you were involved with --

23 A. Well, I mean, that's my -- that's
24 just my summary of my --

25 Q. All right. I want to go -- just

1 see if this jars your memory. The
2 second-to-last paragraph on that page, that
3 same page --

4 A. Uh-huh.

5 Q. -- near the end of that
6 second-to-last paragraph it says, The review
7 confirmed that Dr. Franklin authorized 15,298
8 controlled substance prescriptions during the
9 period of 4/10/06 through 6/4 of '08.
10 Overholt's Pharmacy alone dispensed 50 percent,
11 or 7,660 prescriptions.

12 Were those of Dr. Franklin's
13 prescriptions?

14 A. I believe so. I think this was
15 written by George Pavlich.

16 Q. Okay. And does that jog your
17 memory of the extent of prescribing of
18 controlled substances that Dr. Franklin was
19 involved with and why this was such a complex
20 investigation?

21 A. Yes.

22 Q. Do you know from your involvement,
23 Agent Edwards, that this investigation was
24 actually instigated by complaints from
25 pharmacists?

1 A. I don't recall where it came from.
2 I would believe that there were numerous
3 complaints.

4 Q. This is noted as a joint
5 investigation of both Dr. Franklin and the
6 Overholt Pharmacy. Was that unusual, in your
7 experience, to do a joint investigation of both
8 the pharmacy and the doctor at the same time?

9 A. That was the first investigation I
10 was involved in of this type.

11 Q. Page 5737 in the middle references
12 Dr. Franklin not accepting insurance. Do you
13 recall that, that that was one of the things
14 that was a concerning nature --

15 A. Yes.

16 Q. -- in the investigation, that he
17 was requiring patients to pay with cash?

18 A. Yes, I recall that.

19 Q. Okay.

20 A. I recall envelopes of cash.

21 Q. Down -- the next paragraph below,
22 paragraph 1, 2, 3 -- it says, Dr. Piszal stated
23 that the most often used pharmacy, Overholt's
24 Pharmacy, is also a cause for concern since no
25 pharmacy he has ever dealt with would fill the

1 number of different simultaneously prescribed
2 sustained release opioid preparations, doses,
3 and quantities.

4 Was Dr. Piszal the expert retained in
5 this investigation to assist in reviewing?

6 A. Yes.

7 Q. And did you need an expert -- he
8 was an expert pharmacist, he or she?

9 A. He was a -- he was a medical
10 doctor. I don't know -- I want to say he might
11 have also been a pharmacist. I can't recall.

12 Q. Okay. But is that something the
13 investigators felt that they needed in order to
14 complete this investigation of Dr. Franklin and
15 Overholt, you actually needed a medical doctor
16 to help with analyzing the prescription?

17 A. In this case, yes.

18 Q. Page 5739 of the search warrant,
19 sir. In the middle paragraph, 5, it says, This
20 is a known diversion tactic used by drug
21 seekers to prevent multiple prescriptions from
22 being questioned and confiscated at one
23 pharmacy by splitting them between multiple
24 pharmacies.

25 What can you tell us about this

1 diversion tactic used by drug seekers? What
2 does that mean? How do they avoid detection?
3 Is that a way to avoid detection?

4 A. By going to multiple pharmacies?

5 Q. Well, splitting the prescription,
6 I guess.

7 A. Right. Like, in other words, he
8 got multiple prescriptions and filled some at
9 one pharmacy and some at another.

10 Q. Okay. And that's a diversion
11 tactic because --

12 A. Because --

13 (Reporter interrupted.)

14 A. Had they all been taken to one
15 pharmacy, that would have been a red flag.

16 BY MR. BARNES:

17 Q. Okay. Have you seen that in your
18 experience as an agent, that people interested
19 in diversion will split their prescriptions in
20 order to avoid detection at single pharmacies?

21 A. Yes.

22 Q. Now, do you recall, Agent Edwards,
23 during this investigation, before Dr. Franklin
24 was fully prosecuted -- I guess you couldn't
25 fully prosecute him because his wife murdered

1 him; is that right?

2 A. Yes.

3 Q. But while the investigation was
4 going on, did you at any time advise pharmacies
5 in the area to not fill Dr. Franklin's
6 prescriptions because of this substantial
7 evidence of diversion as a pill mill?

8 A. Not that I recall.

9 Q. Why would --

10 (Technical interruption.)

11 MR. BARNES: Who's ever speaking,
12 please turn yourself on mute. Thank you.

13 BY MR. BARNES:

14 Q. Agent Edwards, would investigators
15 normally tell pharmacists in the area to stop
16 dispensing for a doctor under investigation or,
17 you know, pharmacy under investigation?

18 A. No.

19 Q. Why not?

20 A. Well, because you don't want the
21 doctor to know that they're under
22 investigation. If we're investigating a doctor
23 who we suspect is doing something, we want to
24 perform our investigation without being tipped
25 off. So if we were to tell a pharmacist that

1 we're investigating a certain doctor, and then
2 they stop filling prescriptions, inevitably
3 somebody's going to tell the doctor we're not
4 filling scripts because the Board of Pharmacy's
5 looking at you. So that's why. That's why.

6 Q. Okay. So as far as if any
7 pharmacists in the area are concerned, you
8 don't tell them that somebody's under
9 investigation so they may or may not fill
10 prescriptions from that doctor under
11 investigation?

12 A. Correct. It's up to them to use
13 their professional judgment.

14 Q. I see. When is it that they
15 should stop filling for that doctor? Is it
16 when they're actually criminally convicted and
17 their license is revoked?

18 A. Well, certainly they should stop
19 at that point --

20 Q. Right.

21 A. -- when their license is revoked.
22 Prior to that, they should use their
23 professional judgment to evaluate each
24 prescription. I mean, there's been instances
25 where a doctor is under investigation for a

1 small portion of the practice and there's a
2 larger portion of the practice that's
3 legitimate. So to say don't ever fill a
4 doctor's prescription would not be prudent in
5 that situation.

6 So just going back on what I said,
7 you don't ever tell a pharmacy that a doctor's
8 under investigation because it could compromise
9 the investigation.

10 Q. Okay. It sounds like there's also
11 patient concerns, there might be legitimate
12 patients sprinkled in there amongst --

13 A. Correct.

14 Q. -- doctor shoppers?

15 A. Correct.

16 Q. On the top of page 5741, there's
17 an indication that the agent in charge, I
18 think, was George Pavlich, met with pharmacists
19 from Rite-Aid, Giant Eagle, and Walmart in
20 Middlefield, Ohio.

21 Do you see that?

22 A. Yes.

23 Q. It says, These same pharmacists
24 stated they filed many complaints with the
25 local police and former Agent Bodi since 2006

1 regarding excessive quantities and combinations
2 of controlled drugs prescribed by Dr. Franklin
3 to his patients. These various pharmacists in
4 Middlefield, Ohio confirmed that they refused
5 to dispense medication for the majority of
6 patients issued prescriptions by Dr. Franklin.
7 The pharmacists all stated that the patients
8 they've turned away were now having their
9 prescriptions dispensed at Overholt's Pharmacy.

10 Were you aware of that as part of
11 this investigation, that pharmacists from Giant
12 Eagle, Rite-Aid, and Walmart had met with this
13 agent and given him this information that they
14 had been complaining since 2006?

15 A. I'm sure I was aware at some
16 point, but I didn't recall that until reading
17 this.

18 Q. Did you deal with any of the
19 pharmacists at Giant Eagle, Rite-Aid, or
20 Walmart as part of the Franklin/Overholt
21 investigation?

22 A. I don't recall.

23 Q. That was a pretty long
24 investigation, pretty thorough investigation;
25 is that correct?

1 A. Yes.

2 Q. The individuals that were targeted
3 for prosecution in that investigation were
4 Dr. Franklin and Overholt; is that right?

5 A. I believe so.

6 Q. Were any other individuals or
7 entities targeted for prosecution in that
8 matter?

9 A. I don't recall.

10 Q. We know Dr. Franklin couldn't be
11 prosecuted because of his untimely death, but
12 the Overholt Pharmacy was charged, was it not,
13 with criminal behavior?

14 A. I did not handle that portion of
15 the investigation. I don't recall what
16 happened with that.

17 Q. Okay. The next exhibit,
18 Exhibit 20, can you identify this exhibit for
19 us? Do you recognize it? Have you ever seen
20 it before?

21 A. It looks like an inspection report
22 completed by George Pavlich.

23 Q. Of the Overholt Pharmacy in
24 Warren, Ohio?

25 A. Yes.

1 Q. Were you part of this inspection
2 or did you review it in connection with your
3 investigative work on the Franklin/Overholt
4 investigation?

5 A. I don't recall.

6 Q. Can you tell me by looking at it
7 whether this is indicative of a bad inspection
8 of a pharmacy; in other words, this is not the
9 kind of inspection you ever want to receive if
10 you're a pharmacist?

11 A. I would have to read it word for
12 word.

13 Q. I'll have Mr. Pavlich do that.

14 A. Okay.

15 Q. There's a similar report at
16 Exhibit 20, if you flip backwards.

17 A. This is Exhibit 20.

18 Q. Oh, I'm sorry. I meant 53.

19 MR. THOMAS: I'm sorry. Do you mean
20 Exhibit 53 then?

21 MR. BARNES: Exhibit Edwards 53, yes.

22 MR. THOMAS: Okay.

23 A. Okay. I see that.

24 BY MR. BARNES:

25 Q. Can you identify it as an

1 inspection report prepared by Mr. Pavlich?

2 A. Yes.

3 Q. Would you have to read it to
4 testify about it?

5 A. Yes.

6 Q. And recall? All right.

7 A. Yes. I don't see my signature on
8 there, so I don't believe I was present. This
9 was -- this was before I was hired by the
10 Board, so I would not have been present at this
11 inspection.

12 Q. Okay. If you look at Exhibit 29,
13 there's a reference to two pharmacists
14 associated with the Overholt pharmacist --
15 Pharmacy, Andrea Luchette and Robert Graves
16 being criminally prosecuted. Did you play any
17 part in their criminal prosecutions of those
18 two Overholt pharmacists?

19 A. Not that I recall. That would
20 have been Agent Pavlich.

21 Q. If you look at Exhibit 30, there's
22 a presentence report for a Joseph Michael
23 Harrington. Do you recognize that name?

24 A. I do.

25 Q. Who is he?

1 A. He is a -- well, I don't know if
2 he still is. He was a resident of Lake County.
3 He is someone who I had a case on when I worked
4 for LCNA and then again when I worked for the
5 Board of Pharmacy. He was -- he was a doctor
6 shopper as well as a patient of Dr. Franklin;
7 just a frequent flier, I guess you could say.
8 He was a name that popped up regularly.

9 Q. He was involved with diversion of
10 pharmaceuticals in Lake County --

11 A. Correct.

12 Q. -- in this time period?

13 A. Yes.

14 Q. I think we touched on this
15 earlier, Mr. Edwards, Agent Edwards, that from
16 time to time pharmacists -- well, actually,
17 many of your leads came from pharmacists in
18 terms of your investigations; is that right?

19 A. Yes.

20 Q. If you look at Exhibit 21, there's
21 an example -- there's an email. Why don't you
22 take a look at it?

23 A. Yes.

24 Q. It's an email. Do you recognize
25 it as an email you sent to Board of Pharmacy

1 agents on or about November 3rd of 2011?

2 A. Yes.

3 Q. And in it you're reporting that a
4 Walmart pharmacist called you and reported a
5 forgery of a prescription that he or she had
6 discovered?

7 A. Correct.

8 Q. Is this a good example of the type
9 of leads that the pharmacists in Lake and
10 Trumbull County would provide to you as an
11 agent of LCNA or the Board?

12 A. Yes. This was actually in
13 Ravenna, Portage County, but this -- we did
14 receive things like that from pharmacists in
15 Lake and Trumbull as well, to my knowledge.

16 Q. Do you recall working with a
17 pharmacist at Walmart who would advise you or
18 call you and tell you about problems like this
19 in the pharmacy?

20 A. I don't recall specific examples.

21 Q. All right. If you look at
22 Exhibit 22, this appears to be another one of
23 your email chains?

24 A. Uh-huh.

25 Q. Do you recognize it as such?

1 A. Yes.

2 Q. And it appears to be referencing
3 the Goertler --

4 A. Yes.

5 Q. -- Goertler brothers. Do you
6 recall them?

7 A. I do.

8 Q. What were they involved with, and
9 what did you investigate them for?

10 A. They were doctor shopping. They
11 were -- at one point they -- I think they were
12 manufacturing fraudulent prescriptions on a
13 computer and then passing them around to other
14 people. They were names well known to law
15 enforcement in Lake County.

16 Q. Were you able finally to
17 successfully prosecute them?

18 A. I believe at least one of them. I
19 can't remember if we got them both or just one.

20 Q. Do you know how that investigation
21 started? Did somebody provide a lead?

22 A. I do not recall.

23 Q. Go to Exhibit 23 and 24. They're
24 kind of related. Can you identify these as
25 your emails --

1 A. Yes.

2 Q. -- related to certain
3 investigations?

4 A. Yes.

5 Q. Can you tell us what
6 investigations they related to and what you
7 recall generally about these investigations?

8 A. Yes. They -- that involved -- at
9 first I didn't know this, but ultimately it
10 ended up that Dr. Tony Carman was befriended by
11 Mohammad Saedi and she was writing fraudulent
12 prescriptions for Mr. Saedi and all these other
13 names of people who didn't exist. And he was
14 passing the prescriptions at pharmacies around
15 northeast Ohio. So the case was made against
16 Mr. Saedi and Dr. Carman, and they both went to
17 prison.

18 Q. Exhibit 24 seems to indicate that
19 these prescriptions were being filled at the
20 Hillcrest Atrium Pharmacy and the Mantua
21 Pharmacy.

22 Do you see that?

23 A. You said Exhibit 24?

24 Q. Yes.

25 A. Okay. I see that.

1 Q. Are those independent pharmacies?

2 A. Yes.

3 Q. Go to Exhibit 25, please.

4 A. Okay.

5 Q. This is a news report of a medical
6 examiner issuing warning about fake oxycodone
7 pills laced with Fentanyl in about December of
8 '18?

9 A. Yes.

10 Q. Do you have any knowledge about
11 this matter; if not the press report itself,
12 but generally?

13 A. Generally, I am aware that
14 fraudulent counterfeit oxycodone prescriptions
15 have been circulated in the past several years.

16 Q. In Lake and Trumbull Counties?

17 A. I'm aware of Lake. I don't know
18 about Trumbull.

19 Q. Okay. Go to Exhibit 26, please.

20 A. I'm sorry. I don't have specific
21 knowledge of these being in Lake County, but I
22 do know they were in Cuyahoga County.

23 Q. Okay. Did you from time to time
24 do investigations that indicated that scripts
25 were coming in from outside the counties?

1 A. From time to time, yes.

2 Q. Is Exhibit 26 an example of one of
3 your investigations in that regard?

4 A. Yes, it appears that way.

5 Q. Go to Exhibit 27, please. You're
6 listed there as the sender of an email on
7 April 11 of 2012.

8 Do you see that?

9 A. Yes.

10 Q. And this involved a search warrant
11 for Dr. Harper --

12 A. Correct.

13 Q. -- responding to Chris Begley
14 below --

15 A. Yes.

16 Q. -- saying he faxed out a notice to
17 our pharmacies on Dr. Fedoroko?

18 A. Yes.

19 Q. Do you recall that? What do you
20 recall about this incident?

21 A. I don't recall that name Fedoroko,
22 but this is just -- this is just sharing
23 information with my former partner about
24 something that was going on in the area.
25 Dr. Harper was down in Summit County, I

1 believe.

2 Q. It says the Summit area pharmacies
3 have stopped filling his scripts. It appeared
4 that they were -- because of that, they were
5 moving east, I guess, towards Lake and Trumbull
6 Counties. Is that the purpose of this notice?

7 A. I believe so.

8 Q. On Exhibit 28, another one of your
9 emails dated April 26 of 2013, referencing a
10 Dr. Lalli?

11 A. Yes.

12 Q. There's a reference in there
13 saying, For obvious reasons, we cannot share
14 the information with the pharmacies.

15 Do you see that in the middle?

16 A. Yes.

17 Q. Why couldn't you share the
18 information? Is that for what you told me --
19 the reason you told me earlier, which is, you
20 don't want to tip the doctor off?

21 A. Correct, we don't want to
22 compromise the investigation.

23 Q. Okay. Exhibit 33. Well, go to
24 29. I'm sorry. Oh, we've already covered
25 this. This is the prosecution of the Overholt

1 pharmacists, Luchette and Graves. We covered
2 30. 31. 32.

3 Go to 33.

4 A. Okay.

5 Q. Is this your email to -- why don't
6 you tell me what it is? It's an email from you
7 to whom?

8 A. To Angela Garofalo, who is a
9 district manager for Giant Eagle.

10 Q. And why were you sending her this
11 email?

12 A. To make her aware of this case
13 that I was working on and to see if they had
14 any fraudulent prescriptions that this woman
15 was passing.

16 Q. Did they, do you recall?

17 A. I don't believe so.

18 Q. Do you know Angela Garofalo?

19 A. I do, yes.

20 Q. And she's a district leader for
21 Giant Eagle?

22 A. Correct.

23 Q. Do you find her to be competent
24 and cooperative and professional in dealing
25 with the Board?

1 A. Yes.

2 Q. Go to Exhibit 34. It's a search
3 warrant for John Mullins. Did you have
4 anything to do with that investigation?

5 A. I did not.

6 Q. Then go to 35. This is a news
7 release related to Dr. Masters, Dr. Sherman,
8 and Dr. Theisler in Trumbull County?

9 A. I have no knowledge of this.

10 Q. Okay. Go to 36.

11 A. Okay.

12 Q. There's a reference to you doing
13 your first solo inspection. I guess you were
14 pretty new at the Board at the time?

15 A. Yes. That would have been -- I
16 got hired in November, so two months after I
17 got hired.

18 Q. 37, can you identify 37 for us?

19 A. That's a letter from my former
20 director at Lake County Narcotics to Aaron
21 Graham, the vice president for corporate
22 security for Purdue.

23 Q. Was the LCNA seeking grant funding
24 from Purdue Pharmaceuticals in connection with
25 law enforcement efforts in Lake County?

1 A. Yes.

2 Q. Did you get the grant?

3 A. I believe we did.

4 Q. And did you use it for law
5 enforcement?

6 A. Yes. If I recall, we did it,
7 that's what it was used for.

8 Q. Go to Exhibit 39, please. I'm
9 sorry. 38. Do you recognize this as a
10 publication of the Department of Public
11 Health --

12 A. Yes.

13 Q. -- for Ohio?

14 A. Yes.

15 Q. Do you use or refer to these in
16 your job as Ohio Board of Pharmacy agent?

17 A. Yes.

18 Q. There's an indication on the first
19 page of this exhibit that as of -- in 2019,
20 illicit fentanyl or fentanyl analogs were
21 involved in 76.2 percent of 2019 overdose
22 deaths, often in combination with other drugs.

23 Is that consistent with your
24 experience as an agent, this is what was going
25 on in Ohio in 2019?

1 A. Yes.

2 Q. And is illicit Fentanyl a problem
3 in Lake and Trumbull Counties at the present
4 time?

5 A. At the present time, I don't know.
6 That's not -- I don't investigate the illicit
7 substances.

8 Q. Okay. Go to page 7 of this
9 report. At the top it says, Illicit Fentanyl
10 or Fentanyl analogs were involved in 76.2
11 percent of 2019 unintentional overdose deaths
12 often in combination with other drugs.

13 Did that information have any
14 pertinence to you as an agent with the Board?

15 A. In what way?

16 Q. Well, did it affect your
17 investigations or did it make you want to
18 change the way you were investigating things or
19 anything?

20 A. I don't think it changed any
21 investigative techniques. Now, personally, I
22 was involved in the early intervention side of
23 things from 2018 till now. So, I mean, it made
24 me want to get people help, but it didn't
25 change the way I did my investigations.

1 Q. All right. Do you know if that's
2 accurate or not, that it was illicit Fentanyl
3 or Fentanyl analogs that were involved with
4 76.2 percent of 2019 unintentional overdose
5 deaths?

6 A. I don't have a reason to doubt the
7 Department of Health's data.

8 Q. Would you look at Exhibit 39,
9 please?

10 A. Okay.

11 Q. Are you familiar with this
12 Walgreens pharmacist by the name -- I believe
13 his name is Stossel?

14 A. Yes.

15 Q. What can you tell us about your
16 relationship with Mr. Stossel or your dealings
17 with him?

18 A. Well, I had -- I had known him
19 since -- pretty much since I started at Lake
20 County Narcotics Agency and continued to know
21 him in my role as a Pharmacy Board agent.

22 Q. And he was at all times a
23 Walgreens pharmacist?

24 A. Yes, I believe so.

25 Q. Did Mr. Stossel provide

1 investigative leads to you when he encountered
2 problems in the pharmacy as evidenced by
3 Exhibit 39?

4 A. Yes.

5 Q. Did anything come of this lead
6 that he provided to you in Exhibit 39 about
7 altered prescriptions?

8 A. I don't recall whatever became of
9 it.

10 Q. Exhibits 40 and 41, they are more
11 Walgreen pharmacists emailing you, one about a
12 Dr. Christopher James and a alprazolam
13 prescription, and the other informing you -- on
14 Exhibit 41 informing you of another problem
15 prescription.

16 Do you see those emails?

17 A. Yes.

18 Q. Again, are these just simply
19 examples of Walgreens pharmacists giving notice
20 to you of people trying to pass bad scripts or
21 forging prescriptions?

22 A. Yes.

23 Q. Were the Walgreens pharmacists
24 generally cooperative with you in providing
25 leads for problem prescriptions?

1 A. Yes.

2 Q. Exhibit 42, this is an arrest of a
3 Marlene T. in the Walgreens drive-up window in
4 the, I guess, Painesville Walgreens involving a
5 Vicodin prescription?

6 A. Yes.

7 Q. Do you recall this incident?

8 A. Only after reading the email. I
9 just know the name because she's someone who we
10 arrested multiple times.

11 Q. And in this instance, did the
12 Walgreens pharmacist call you so that you could
13 be there when she came through the drive-up
14 window and you could arrest her?

15 A. I don't know if that's how it went
16 down or if they knew she was going to pick it
17 up. I don't know how they knew she was going
18 there.

19 Q. Exhibit 43 is a presentence report
20 for an individual by the name of Joseph
21 Sosenko. Do you recognize that name?

22 A. Vaguely.

23 Q. Page 2 of his report references a
24 registered pharmacist, Diane Morris, from the
25 Walgreens pharmacy in Eastlake. Does that

1 refresh your recollection that it was a
2 Walgreens pharmacist that instigated this
3 investigation which led to the successful
4 criminal prosecution of Mr. Sosenko?

5 A. Yes.

6 Q. Exhibit 44, report of
7 investigation of Dorothy Rinehart. Do you
8 recognize that name and were you involved in
9 this prosecution?

10 A. Yes. I believe that was one of my
11 very first cases of my career.

12 Q. And did you work with a Walgreens
13 pharmacist in this investigation, Melanie
14 Burlinghaus on page 2?

15 A. Yes.

16 Q. And did the Walgreens pharmacist
17 provide information that led to the successful
18 prosecution of Ms. Rinehart?

19 A. Yes, it looks like it.

20 Q. If you go to 45, this is a report
21 of investigation of Roxanne Figoli?

22 A. Okay.

23 Q. Were you involved with that
24 investigation?

25 A. Yes.

1 Q. And was that as indicated on
2 page 2 instigated by a Walgreens pharmacist --
3 let me see -- Todd Biedenheim at Walgreens?

4 A. It was initiated by a pharmacist
5 from Medic Drug, and then additional
6 information was provided by a Walgreens
7 pharmacist, yes.

8 Q. Okay. And that led to the
9 successful prosecution of Ms. Figoli for crimes
10 related to pharmaceutical diversion?

11 A. Yeah, I don't recall the outcome
12 of the case, but that's what she was
13 investigated for.

14 Q. Exhibit 46, December 2000 report
15 of investigation of Marlea Ciarlillo?

16 A. Yes.

17 Q. Were you involved in that
18 investigation?

19 A. Yes.

20 Q. And was that also received from a
21 Walgreens pharmacist --

22 A. Yes.

23 Q. -- the lead on that?

24 A. Yes.

25 Q. And that was -- what was the name

1 of the pharmacist?

2 A. Teresa Zienka.

3 Q. And she called about a phony
4 prescription being passed by Ms. Ciarlillo at a
5 Walgreens pharmacy?

6 A. Yes.

7 Q. Do you know if that led to a
8 successful prosecution?

9 A. Yes, it did.

10 Q. Exhibit 47, sir. It's actually a
11 duplicate, so we can skip it.

12 Exhibit 48 is a TAG Law
13 Enforcement Task Force. Can you identify this
14 exhibit for us involving a Leslie Bas, B-a-s?

15 A. I don't know that I was -- I don't
16 believe I was involved in that. That doesn't
17 ring a bell.

18 Q. Doesn't ring a bell?

19 A. No.

20 Q. The reference on page 2 to Erica
21 Kremer at the Rite-Aid Pharmacy, does that ring
22 a bell to you that a Rite-Aid pharmacist
23 instigated this investigation?

24 A. No, I don't recall this case.

25 Q. You don't recall this matter?

1 Okay.

2 A. No.

3 Q. Exhibit 49, did you have anything
4 to do with this investigation, doctor shopping
5 investigation of a guy named Daniel Bayus?

6 A. I don't recall.

7 Q. Hometown Pharmacy, page 3646, for
8 this investigation, it's a reference to a
9 Walgreens pharmacist providing information to
10 assist in this investigation. Does that ring a
11 bell to you at all?

12 A. It does not.

13 Q. Exhibit 50, is this your email --

14 A. Yes.

15 Q. -- announcing that Dr. Lalli had
16 been successfully prosecuted --

17 A. Yes.

18 Q. -- and surrendered his license?

19 A. Yes.

20 Q. Exhibit 53, I think we've seen
21 this before. This is the Overholt Pharmacy.
22 Skip that.

23 Finally, Exhibit 54, this is a
24 Pavlich -- I take it you don't recognize
25 Exhibit 54?

1 A. No. That was before my
2 employment.

3 MR. BARNES: All right. I don't
4 have any further questions, Agent Edwards.
5 Counsel for Walgreens and/or Rite-Aid and/or
6 CVS have reserved some time to ask you some
7 questions. So why don't we take -- is
8 everybody good with a ten-minute break and we
9 can resume with -- Sharon, are you on the line?
10 Do you want to ask questions?

11 MS. DESH: Yes, let's take a
12 break, and I can start in ten minutes.

13 MR. BARNES: Okay. Thank you.
14 Thank you, Agent Edwards.

15 THE WITNESS: You're welcome.

16 THE VIDEOGRAPHER: Off the record,
17 2:47.

18 (Off the record.)

19 THE VIDEOGRAPHER: We're going on
20 the record at 12:58 -- I'm sorry. 2:58.

21 EXAMINATION

22 BY MS. DESH:

23 Q. Good afternoon, Mr. Edwards.
24 Thanks for being with us today. My name is
25 Sharon Desh, and I'm going to be asking you

1 some questions on behalf of Walgreens. I will
2 try not to cover anything that we've covered
3 this morning, but just turn back to a couple of
4 topics as it relates to my client.

5 A. Okay.

6 Q. Can you turn -- do you have
7 Exhibit 19 in front of you?

8 A. Yes.

9 Q. Okay. And can you turn to the
10 bottom of the page ending in 5760? It's about
11 three-quarters of the way through.

12 A. Okay.

13 Q. And just to orient you, Exhibit 19
14 deals with the investigation of Dr. Franklin.
15 The bottom of page 5760 it says, On July 27th,
16 2008, this agent spoke with Walgreens pharmacy
17 manager Doug Stossel.

18 I believe you stated that you have
19 been familiar with Mr. Stossel for a long
20 period of time; is that correct?

21 A. Yes.

22 Q. What's the nature of your
23 relationship with him?

24 A. Well, I knew him as a pharmacist
25 first and then we became Facebook friends, and

1 he just passed away on Sunday. So that's
2 pretty much the extent of it. It was a
3 professional relationship and I would run into
4 him occasionally in -- you know, in the area.
5 He lived near me.

6 Q. And I'm aware that Mr. Stossel had
7 some health issues that caused him to retire
8 from the practice of pharmacy. Can you
9 describe a little bit about your relationship
10 with him while he was a pharmacist, what types
11 of things he would bring to you, and generally
12 what you thought of him and his practice?

13 A. I thought he was a great
14 pharmacist. He was very diligent. He would
15 give me calls whenever he had a question about
16 a patient or, you know, had something that he
17 was unsure about. I mean, he -- I think he
18 used me as a resource, and I used him as a
19 resource, and it was a good working
20 relationship.

21 Q. And I think that we saw both of
22 Mr. Stossel and a number of other Walgreens
23 pharmacies -- pharmacists that oftentimes those
24 tips can aid in your investigation and lead to
25 convictions of people engaged in criminal

1 activity; is that correct?

2 A. Yes.

3 Q. Okay. Would you say that the --
4 speaking of the time that you worked for Lake
5 County, do you think that the majority of the
6 investigations that you conducted of
7 pharmaceutical diversion began with a tip from
8 a pharmacist?

9 A. Yes, I would say that's accurate.

10 Q. Returning to Exhibit 19, it looks
11 like Mr. Stossel alerted the Board that he had,
12 it says, concerns with numerous Dr. Franklin
13 patients. Then the agent, is this -- was this
14 you, or is this Agent Pavlich, do you recall?

15 A. Yes. When it refers to this
16 agent, that refers to George Pavlich.

17 Q. Okay. It says, This agent
18 contacted Pharmacist Stossel and advised him
19 that he should dispense the prescriptions for
20 Dr. Franklin even though an investigation was
21 ongoing unless he has a problem because of the
22 medications in combinations.

23 Do you see that?

24 A. Yes.

25 Q. And is that consistent with your

1 testimony earlier that, in general, the Board
2 did not want to tip off individuals or doctors
3 who were under investigations by telling
4 pharmacists to stop filling for them?

5 A. I don't know what his intent was.
6 You'd have to ask Agent Pavlich.

7 Q. Okay. But you do see that the
8 instruction was to continue to dispense for
9 Dr. Franklin even while he was under
10 investigation?

11 A. Correct.

12 Q. Okay. And then just to finish on
13 Exhibit 19, Mr. Stossel, in response to this
14 advice, did state that he would no longer
15 dispense for Dr. Franklin.

16 Do you see that?

17 A. Correct. Yes.

18 Q. And that was his prerogative as a
19 pharmacist using his professional judgment,
20 correct?

21 A. Correct.

22 Q. Okay. We talked a little bit
23 earlier about some of the, I think, things you
24 would investigate in your work for Lake County.
25 And you talked a little bit about illegal

1 processing. Can you remind us what illegal
2 processing is?

3 A. Sure. That's essentially writing
4 a fake prescription or altering a legitimate
5 prescription, like changing the quantity or
6 date or name or anything like that. So it's
7 forging a prescription.

8 Q. And is illegal processing or
9 forging of a prescription, is that a crime?

10 A. Yes.

11 Q. Okay. And we also spoke about
12 doctor shopping. Can you provide your
13 definition, sitting here today, of doctor
14 shopping?

15 A. Sure. That's when someone goes to
16 multiple physicians for either legitimate or
17 nonlegitimate reasons to -- with the intent to
18 overlap prescriptions and get additional
19 medication, more than -- basically they deceive
20 doctors. They go to one doctor, get a
21 prescription, go to another doctor who doesn't
22 know that they just went to the first doctor
23 and they get another prescription, that type of
24 thing.

25 Q. And is the act of doctor shopping

1 and that deception, is that also a crime?

2 A. Yes.

3 Q. Okay. We spoke a little bit about
4 pill mills and the difference between a pill
5 mill and a pain management clinic. I think
6 that -- would you agree that there are --
7 speaking specifically of pain management
8 clinics, there can be many reasons why a
9 particular doctor might write more
10 prescriptions for opioids, for example -- maybe
11 legitimate reasons that he would do that than
12 another doctor?

13 A. Yes.

14 Q. Okay. For example, I think you
15 said if they're near a hospice center, maybe if
16 they're an oncologist; are those examples of
17 doctors who might write more prescriptions for
18 opioids than other doctors?

19 A. Yes.

20 Q. Okay. Would you also agree that
21 it's possible that certain pharmacies might
22 fill more prescriptions legitimately for
23 opioids than other pharmacies, depending on
24 where they're located and the type of pharmacy
25 that they might be?

1 A. Yes.

2 Q. For example, if they're also near
3 a hospital or a hospice center or if they're
4 24 hours a day?

5 A. Correct, yes.

6 Q. And I think you also mentioned
7 that even for the doctors that were under
8 investigation or some portion of their practice
9 was illegitimate, those doctors may still have
10 legitimate patients who truly do need opioid
11 prescriptions; is that correct?

12 A. Correct.

13 Q. And that's why you would not
14 instruct a pharmacist to refuse to fill for a
15 doctor as a blanket rule, but to exercise their
16 professional judgment with respect to each
17 individual prescription; is that correct?

18 A. That's one of the reasons, yes.

19 Q. I want to talk a little bit --
20 well, before we end that, would you agree that
21 most doctors who prescribe opioids are just
22 good people trying to do the right thing?

23 A. Well, I wouldn't say good people.
24 I would say good doctors. I don't know who
25 they are as people, but I would say the vast

1 majority of prescribers are legitimate, and
2 it's a small fraction of prescribers who are
3 doing things illegal or illegitimate.

4 Q. And would you say the same for
5 pharmacies and pharmacists, that the vast
6 majority of pharmacies and pharmacists are good
7 and executing their responsibilities
8 faithfully?

9 A. Yes.

10 Q. Okay. I want to turn for a moment
11 to a discussion of diversion that we engaged in
12 a little bit earlier just to understand -- I
13 believe you said that your definition of
14 diversion is when a legitimate drug exits the
15 legitimate supply chain. Am I paraphrasing
16 that correctly?

17 A. Yes.

18 Q. Okay. Have you had a situation
19 where -- I believe you said where you've
20 prosecuted somebody for stealing drugs from a
21 patient who had a legitimate prescription?

22 A. Yes.

23 Q. Okay. So sometimes we think about
24 that as somebody who's taking drugs out of a
25 medicine cabinet that belong to somebody else,

1 correct?

2 A. Right.

3 Q. In that instance where drugs are
4 taken out of the medicine cabinet, would you
5 agree with me that the doctor who wrote the
6 prescription and the pharmacist who filled it
7 and the patient who received it, those are not
8 the individuals engaging in diversion, it's the
9 person who has stolen the pills; is that
10 correct?

11 A. Correct.

12 Q. Okay. So we spoke a little bit in
13 particular about Mr. Stossel. Are you familiar
14 with any other Walgreens pharmacists? I think
15 we mentioned -- we looked at Teresa Zienka and
16 also Julie Demay.

17 A. Sure.

18 Q. What is your relationship with
19 those two individuals?

20 A. Well, I know them professionally.
21 One went to college with my wife, and another
22 is a neighbor.

23 Q. Okay. And with respect to
24 Ms. Zienka and Ms. Demay, do you also -- well,
25 I'll back up. Do you also know Amy Stossel?

1 A. Yes.

2 Q. Doug's wife. And she's a current
3 Walgreens pharmacist; is that your
4 understanding?

5 A. Correct.

6 Q. And do you understand that
7 Ms. Zienka and Ms. Demay and Ms. Stossel have
8 also reported fraudulent behavior and
9 suspicious behavior to you, and that's assisted
10 you in combatting diversion?

11 A. Yes.

12 Q. I think we saw some examples
13 earlier where Walgreens pharmacists would even
14 time their calls to the police such that the
15 police could be waiting for a suspect when that
16 suspect showed up at Walgreens. Do you
17 remember that?

18 A. I don't remember a specific
19 incident, but that has happened at several
20 pharmacies in my career.

21 Q. So is it your experience that the
22 Walgreens pharmacists generally do take the
23 time to, you know, look closely at
24 prescriptions and to reach out to law
25 enforcement when necessary?

1 A. Yes.

2 Q. All right. I want to turn to now
3 some of the Walgreens inspection reports. I
4 promise we'll try to hit them more quickly than
5 the Giant Eagle ones since we know the general
6 parameters. But you were -- were you involved
7 in inspecting Walgreens pharmacies?

8 A. Yes.

9 Q. What was the general sort of time
10 period and geographic scope of your inspection
11 of Walgreens pharmacies?

12 A. The time period was 2008 through
13 present. And, generally speaking, it was
14 pharmacies in the northeast part of the state,
15 but I have done some others in other areas of
16 the state.

17 Q. Did your inspections cover both
18 Lake and Trumbull Counties?

19 A. At various times, yes.

20 Q. Okay. And I think, as we
21 discussed earlier and saw in prior examples, if
22 you found something in the course of your
23 inspection that needed to be corrected, you
24 would document it in the inspection report; is
25 that correct?

1 A. Yes.

2 Q. And is that -- is that important
3 to you to sort of do a thorough job and to let
4 the pharmacy know when something needs to be
5 corrected?

6 A. Yes.

7 Q. To the best of your knowledge,
8 were the inspections of the Walgreens
9 pharmacies generally favorable and positive?

10 A. Yes, generally.

11 Q. Okay. Can you turn to -- and how
12 long, actually, before we turn -- go ahead --
13 how long does an inspection usually take?

14 A. Well, it varies. I mean, a full
15 inspection can take an hour or more. Just --
16 it depends. It depends what you find. It
17 depends, you know, how long you're talking to
18 the pharmacist about different issues. It
19 varies, and it varies depending on the agent as
20 well.

21 Q. Okay. But is that a pretty
22 thorough process of going through and
23 inspecting the pharmacy?

24 A. Yes.

25 Q. And you could take any amount of

1 time that you needed to feel that you had
2 completed the inspection adequately; is that
3 correct?

4 A. Correct.

5 Q. Okay. Can you turn to Exhibit 51?
6 So this should be a document with Bates stamp
7 BOP_MDL2797626.

8 Do you see that?

9 A. Yes.

10 Q. And Exhibit 51 is an inspection
11 report of Walgreens store 4294 in Willoughby,
12 Ohio, and it looks like that's in Lake County,
13 correct?

14 A. Yes.

15 Q. Okay. If you turn to the first
16 page, it looks like the responsible person was
17 Teresa Zienka, who we've already talked about
18 as somebody who you have experience with at
19 Walgreens, correct?

20 A. Correct.

21 Q. Okay. I just want to go through a
22 couple of the items here. So one of the items
23 that you documented was in section 2.2, ID
24 cards. And it looks like a pharmacy intern at
25 Walgreens did not have her ID on her, but that

1 you were able to verify that her license was
2 currently active; is that correct?

3 A. Yes.

4 Q. Okay. So even for -- even for
5 small things, do you find it important to
6 document them for -- so you have a record and
7 so that the pharmacy can make sure that it
8 complies in the future?

9 A. Yes.

10 Q. Can you turn to 6.1?

11 A. Okay.

12 Q. Okay. And, actually, before we go
13 there, on 5.7, it looks like the answer to
14 every single -- or in section 5, Minimum
15 Standards, it looks like the answer to every
16 single one of these questions was yes. And I
17 see no follow-up documented. But 5.7 says, Is
18 there evidence to indicate a problem with
19 staffing levels? And it says yes.

20 Do you know if that was an error
21 or why there's no documentation there?

22 A. I believe that was probably an
23 error. It's -- the manner in conducting these
24 inspections digitally, there's like a drop-down
25 menu, and the cursor must have been off because

1 I don't recall there being an issue at this
2 pharmacy.

3 Q. Okay. And we'll go through a few
4 other reports, but to your knowledge, do you
5 ever recall any issues with staffing levels at
6 Walgreens pharmacies?

7 A. No.

8 Q. In 6.1 for Security it says, Is
9 the security of the pharmacy drugstore adequate
10 to detect and deter drug theft and diversion?
11 And the answer is yes.

12 Can you tell us what you're
13 looking for -- a little bit more about what
14 you're looking for here when you're looking for
15 controls to detect and deter drug theft and
16 diversion?

17 A. Well, are the C-IIs locked up, is
18 there recordkeeping that's accurate, and if
19 something were to go missing, would the
20 recordkeeping find that? Like, for instance,
21 the next time they performed a count of the
22 medication, you know, is it accurate in the
23 sense that they would catch it the next time
24 they counted.

25 Q. And I think you mentioned earlier

1 that you also work sometimes with the -- with
2 Walgreens and other chain pharmacies' loss
3 prevention departments; is that correct?

4 A. Yes.

5 Q. Is the type of activity that the
6 loss prevention department would engage in
7 doing counts of pills and making sure no pills
8 went missing or were unaccounted for?

9 A. Generally the pharmacy employees
10 will do the counting, and then if there were
11 discrepancies, they would report it to loss
12 prevention, who would then come in and do
13 additional checks.

14 Q. Okay. Great. And is that -- is
15 that general process what you're referring to
16 in 6.1 when you're talking about whether the
17 controls of the pharmacy are adequate to detect
18 and deter drug theft and diversion?

19 A. Yes.

20 Q. Do you know Laurie Zaccaro from
21 Walgreens?

22 A. Yes.

23 Q. What's your relationship with her?

24 A. She's a loss prevention employee
25 for Walgreens.

1 Q. And has she also reached out to
2 you about potential, you know, suspicious
3 activity at Walgreens? Has she also helped you
4 in the course of your job?

5 A. Yes.

6 Q. In -- can you move down to 6.5?
7 It also says, Has the pharmacy experienced any
8 drug thefts or loss in the last three years?
9 And the answer is no.

10 Do you see that?

11 A. Yes.

12 Q. Okay. And at a high level, in
13 your opinion, why -- or in your experience, why
14 are these types of questions important, talking
15 about detecting and deterring drug theft and
16 diversion and making sure there are no losses
17 at a pharmacy?

18 A. To ensure that drugs are not being
19 diverted.

20 Q. Okay. And to ensure that the
21 chain pharmacies have controls in place to make
22 sure that -- to prevent diversion; is that
23 correct?

24 A. Yes.

25 Q. Okay. Can you turn to -- there's

1 a couple items on here about drug utilization
2 review that we won't touch on because they were
3 addressed earlier, but I'll bring them to your
4 attention quickly. 11.1, do you see that it
5 says, The pharmacists are performing a
6 prospective drug utilization review?

7 A. Yes.

8 Q. And just for the purpose of this
9 question, can you remind us, you know, what
10 that is and why it's important?

11 A. It's part of the dispensing
12 process to fill a prescription and it's
13 ensuring that they're taking all the steps of a
14 DUR to ensure that the prescription should be
15 dispensed.

16 Q. If you go to 18.1, also speaking
17 about DUR in Exhibit 19, Does the pharmacist
18 rely solely on the dispensing software to
19 perform the DUR for prescription dispensing?
20 And it says no.

21 And I take that to be the correct
22 answer that the pharmacist should be doing more
23 than just relying on the software; is that
24 correct?

25 A. Correct.

1 Q. And what other things do
2 pharmacists usually do in addition to relying
3 on the software?

4 A. Personal observations and
5 knowledge that they gain from other sources.
6 It's not just the checkmarks on the -- you
7 know, in the computer, it's other things that
8 they may become aware of related to the patient
9 or that particular prescription that may give
10 them pause.

11 Q. Okay. Great. And so just so I
12 understand, I think you said your testimony is
13 that the practice of pharmacy and the exercise
14 of the pharmacist's judgment, they're not just,
15 I think as you said, checkmarks on a computer,
16 but things that they know and experience in
17 their everyday life and in their interaction
18 with a patient; is that correct?

19 A. Correct.

20 Q. Can you turn to item 19? Item
21 19.2 says, Have the frequency of errors caused
22 a standard of practice issue for the
23 pharmacy -- with the pharmacist or a pharmacy
24 as a whole?

25 Can you explain that a little bit

1 more what you mean by the frequency of errors
2 as related to the standard of practice?

3 A. Generally speaking, that -- I
4 believe that question is asked for instances
5 where there are multiple errors occurring at a
6 pharmacy, and basically it's asked to then
7 further investigate that, like why are all
8 these errors occurring, is it an impaired
9 pharmacist, is it a -- you know, a staffing
10 issue, is it -- like what is causing the errors
11 to take place.

12 Q. Okay. So if you see some
13 threshold of errors, it might give you reason
14 to believe that more investigation is needed?

15 A. Correct.

16 Q. I take it from the way that this
17 is phrased that the threshold is not one, but
18 it might be something more than one. Can you
19 put any context around that?

20 A. I mean, yeah. It could be
21 multiple issues. It could be an elderly
22 pharmacist who, you know, isn't quite there as
23 mentally as they were years ago that's making
24 many errors. So it could be any number of
25 reasons that are causing errors to take place

1 which are -- which are making things unsafe at
2 the pharmacy.

3 Q. Do you have a baseline or a set
4 number of errors that would trigger a standard
5 of practice issue, or does it depend on the
6 context?

7 A. It depends entirely on the
8 context.

9 Q. Okay. But we do see in
10 Exhibit 19, item 19.4, Has a dispensing error
11 occurred in the pharmacy? And the answer there
12 is no.

13 Do you see that?

14 A. Yes.

15 Q. Okay. So we've gone through that.
16 I want to go through a couple other examples.
17 Do you have an extra envelope with you that has
18 exhibits -- a separate envelope with exhibits
19 in it?

20 A. I have a box that says do not open
21 until instructed to do so. Is that --

22 Q. We might be there.

23 MR. BARNES: Should have said do not
24 open till Christmas.

25 MS. DESH: Yeah.

1 THE WITNESS: Yeah, send me this
2 in December. How nice. I've been waiting all
3 day for somebody to tell me to open this.

4 MR. CIACCIO: Sharon, do we have
5 these exhibits either electronically or somehow?

6 MS. DESH: Yes. You know what,
7 they were -- they were delivered by courier to
8 counsel for Mr. Edwards. I'm having a little
9 bit of an issue with my Exhibit Share, but I
10 can probably share my screen if you'd like to
11 see them.

12 MR. CIACCIO: Yes. So no one on the
13 plaintiffs' side got any exhibits. Then, yeah,
14 I'd like to see them.

15 MS. DESH: Okay. I will share my
16 screen, and I'll get them to the court reporter
17 afterwards. I did not see the folder in
18 Exhibit Share to put them.

19 THE WITNESS: Should I go ahead
20 and open --

21 MS. DESH: Yes.

22 THE WITNESS: -- envelope A?

23 MR. CIACCIO: Just for the record,
24 we're going to have an objection to not receiving
25 copies of exhibits, but for the deposition's sake,

1 whatever you can do to share them with me, I'd
2 appreciate it. But we're going to have a standing
3 objection.

4 MS. DESH: Sure. And I did intend
5 to introduce them electronically and there was
6 an issue with the folder, but --

7 MR. CIACCIO: Right. I just thought
8 that the protocol required it to be shared with
9 the parties ahead of time just so people had
10 copies. But --

11 MS. DESH: I don't know if that's
12 true for a third party, but we can -- we'll
13 make sure that we do that.

14 MR. CIACCIO: Yeah, I mean, I'm not
15 sure what to cite to tell you it is or isn't, but,
16 I mean, if you don't think we have to send you
17 exhibits and you don't have to send us exhibits,
18 that's not my understanding. But I'll --

19 MR. APPEL: This is Henry Appel.
20 This is Henry Appel, counsel for Mr. Edwards
21 and for the Board did receive a copy -- I did
22 receive a copy of them, and my understanding is
23 for the MDL standing order is that all parties
24 to the deposition were to receive a copy of the
25 exhibits before the deposition, but that's at

1 least my reading of it.

2 MR. CIACCIO: Yeah, I mean, that's
3 our reading of it, too. So, you know, obviously
4 if there's any depositions that are going to be
5 used -- any exhibits that are going to be used on
6 Monday that we don't have yet -- I know counsel
7 for Giant Eagle gave us all of his exhibits, but
8 if any other -- if there are going to be any other
9 additional exhibits, I would ask they get sent
10 over right away so we have them in advance of the
11 deposition.

12 MS. DESH: Sure. We'll make sure
13 we do that.

14 BY MS. DESH:

15 Q. Okay. So the exhibit that I'm
16 showing you here, I think we'll mark it as
17 maybe Exhibit 55. I'll coordinate with the
18 court reporter on that. This is a -- this is
19 an inspection report from Walgreens store 5822
20 in Painesville, Ohio, in Lake County, from
21 February 18, 2016.

22 Do you see that?

23 A. Yeah. I believe it says 5821,
24 though.

25 Q. 5821. Thank you. And for this

1 inspection report it actually indicates that a
2 written response is required.

3 Do you see that?

4 A. Yes.

5 Q. And just to confirm for Exhibit 51
6 that we were just reviewing, no written
7 response was required, at least not on the
8 cover of the inspection report; is that
9 correct?

10 A. No. It does say written response
11 required.

12 Q. Correct. For the one that we're
13 looking at here?

14 A. Yes.

15 Q. Can you turn back to Exhibit 51
16 that we were looking at previously? And that
17 is the inspection report for Walgreens --

18 A. Yes.

19 Q. -- 4294.

20 A. Yes.

21 Q. And for Exhibit 51, if I'm
22 correct, it does not indicate that any written
23 response is required; is that correct?

24 A. Correct.

25 Q. Okay. And does that mean there

1 were no follow-up issues that you needed to
2 address with the pharmacy after the inspection?

3 A. Correct.

4 Q. Turning back to the inspection
5 report for 5821, and it looks like this might
6 be an excerpt, although I will represent to you
7 that this is how it was produced to us. If you
8 go to item 4, it says -- item 36.4 says, Have
9 appropriate background checks been performed on
10 all employees intending to work in the
11 pharmacy? And then there's an observation
12 that a certain pharmacist or employee did not
13 have -- a pharmacist technician, I should say,
14 did not have a background check performed on
15 her.

16 Do you see that?

17 A. Yes.

18 Q. Okay. And now I'd like to draw
19 your attention to -- stop my share for a
20 minute. This will be the last one. Well --
21 but -- to what we'll mark as Exhibit 56. And
22 this is a document with the Bates stamp
23 BOP_MDL2797836, which is a letter from
24 Walgreens to the Board of Pharmacy stating,
25 This letter and enclosed document are in

1 response to the inspection completed in
2 February 2016. It was stated that we did not
3 have a background check completed on this
4 technician, but enclosed is a copy of that
5 background check, which was located in her file
6 on the day of the inspection.

7 Do you see that?

8 A. Yes.

9 Q. Okay. And is this an example of
10 where there might be a citation or a written
11 response required, but it's later determined
12 that the pharmacy was in compliance and they
13 just needed to find the requisite
14 documentation?

15 A. Yes.

16 Q. Okay.

17 A. So just to clarify, not a
18 citation. Citation is different from a written
19 warning.

20 Q. Thank you. Thank you. That's a
21 good clarification. And maybe just for the
22 record I'll say the letter that we just
23 reviewed is an example where there might be a
24 written response required, but it's later
25 determined that the pharmacy was in compliance

1 and they just needed to find the requisite
2 documentation?

3 A. Correct. Right.

4 Q. Sitting here today, can you --
5 well, backing up for a moment. I think we
6 talked about the fact that when there is a
7 deficiency that you observe, you will document
8 it as part of the inspection report, correct?

9 A. Correct.

10 Q. And sitting here today, can you
11 recall any instance in which an issue that you
12 observed was not resolved to your satisfaction
13 by a Walgreens pharmacy in response to that
14 request?

15 A. Not that I recall.

16 Q. Can you turn to Exhibit 52, which
17 should be in your binder?

18 A. I stop at 51. Oh, no, I'm sorry.
19 Yes.

20 Q. Okay. Exhibit 52 is a document
21 with the Bates stamp BOP_MDL2797783.

22 Do you see that?

23 A. Yes.

24 Q. And this is for store 10569 in
25 Niles, Ohio in Trumbull County, Walgreens?

1 A. Correct.

2 Q. Okay. From March 21st, 2017.

3 A. Yes.

4 Q. Okay. We won't repeat the items
5 that we looked at before. I'll just turn your
6 attention to a couple of items. The first is
7 on 5.7, Minimum Standards, this asks, Is there
8 evidence to indicate a problem with staffing
9 levels? And the answer is no.

10 And I think that's consistent with
11 your prior testimony, that your recollection
12 was that you can't recall an issue with
13 Walgreens staffing levels; is that correct?

14 A. Correct.

15 Q. Okay. Can you turn to item 11.1?

16 A. Yes.

17 Q. Okay. Before we get there, we've
18 looked at some inspection reports for -- from
19 2016, and Exhibit 52 is an inspection report
20 from 2017. And it looks like the format has
21 changed a little bit; not fully, but some of
22 the questions have changed. Can you explain a
23 little bit about why that is, why some of the
24 questions change between reports?

25 A. They just continually update the

1 inspection form. It's --

2 Q. Okay.

3 A. It's a moving document that, as
4 rules change, as things are found that, you
5 know, may be problematic, they add different
6 questions and maybe change the way certain
7 questions are asked.

8 Q. In 11.1 it says, Is there evidence
9 to indicate that a prescription has been
10 dispensed improperly?

11 Do you see that?

12 A. Yes.

13 Q. Okay. And do you see that the
14 answer is no?

15 A. Yes.

16 Q. Sitting here today, do you have
17 any recollection of a Walgreens pharmacy
18 dispensing a prescription improperly?

19 A. I don't have recollection, no.

20 Q. Okay. And sitting here today, do
21 you have any recollection of a Walgreens
22 pharmacy having any dispensing errors that we
23 discussed earlier?

24 A. I know I've investigated some, but
25 I don't have specific recollections.

1 Q. Okay. What is your recollection
2 of what you have investigated with respect to
3 dispensing errors?

4 A. I know I've investigated some at
5 probably all of the different stores, but I
6 don't have specific recollections of the
7 incidents.

8 Q. Okay. And if you had identified a
9 dispensing error, that's something that you
10 would have noted in the inspection report; is
11 that correct?

12 A. Correct. Now, typically we
13 don't -- it's rare to identify a dispensing
14 error while conducting an inspection.
15 Typically we're made aware of a dispensing
16 error and then you go in and conduct the
17 inspection and document the error in the
18 inspection report.

19 So as was seen with the Giant
20 Eagle documents that I reviewed, the vast
21 majority of errors that I investigated came in
22 as a complaint that resulted in an inspection
23 as opposed to the other way around.

24 Q. Okay. But one way or another,
25 those items, if they existed, complaints about

1 dispensing errors, those would be documented by
2 the Board?

3 A. Correct.

4 Q. Okay. I think we talked about
5 this at a high level with respect to Giant
6 Eagle and the other pharmacies. But would you
7 agree that the Walgreens controls in particular
8 generally met the Board's requirements?

9 A. Yes.

10 Q. Would you agree that the Walgreens
11 pharmacies generally complied with Ohio
12 security requirements in particular?

13 A. Yes.

14 Q. And your -- you agree that no
15 Walgreens pharmacy had their license revoked by
16 the Board, to your knowledge?

17 A. To my knowledge, no.

18 Q. To your knowledge, correct, that
19 no Walgreens pharmacy had their license revoked
20 by the Board?

21 A. Correct.

22 Q. Okay. And to your knowledge,
23 that -- agree that no Walgreens pharmacy was
24 cited or disciplined by the Board?

25 A. No pharmacy was disciplined by the

1 Board; is that what you're saying?

2 Q. Yeah.

3 A. Correct.

4 Q. Are you aware of a pharmacist? Is
5 there a reason why you wanted to make that
6 distinction?

7 A. Yes. I mean, I've had cases on
8 Walgreens pharmacists in the past, but not on
9 the particular company or store.

10 Q. Okay. And where there's a case on
11 an individual pharmacist, does the company
12 Walgreens usually cooperate in that case and
13 provide you the information that you need in
14 order to reach resolution?

15 A. Yes.

16 Q. Okay. So as far as you know,
17 picking up on our discussion earlier, the
18 Walgreens pharmacies that you inspected were
19 operating lawfully at all times?

20 A. As far as I know.

21 Q. Okay. And sitting here today,
22 you're not aware of any instance in which a
23 Walgreens pharmacy dispensed a prescription
24 improperly?

25 A. I have no specific memory of that,

1 no.

2 Q. Okay. And you're not aware of any
3 Walgreens pharmacy, sitting here today, that
4 was knowingly filling illegitimate opioid
5 prescriptions, correct?

6 A. Not to my recollection.

7 Q. Okay. And you don't have any
8 evidence that a Walgreens pharmacy was
9 contributing in particular to the diversion of
10 prescription opioids, correct?

11 A. Correct.

12 Q. And I think we talked about your
13 relationship generally with a number of
14 Walgreens pharmacists. Would you agree that
15 Walgreens and the Walgreens pharmacists
16 cooperated with you and would follow your
17 recommendations?

18 A. Yes.

19 Q. And would you agree that Walgreens
20 and the Walgreens pharmacists actively assisted
21 law enforcement with anti-diversion efforts?

22 A. Yes.

23 Q. And to your knowledge, Walgreens
24 was never the subject of any similar --
25 criminal or civil investigation due to alleged

1 diversion of controlled substances, correct?

2 A. Correct.

3 Q. And you never investigated
4 Walgreens pharmacy for violations of the Ohio
5 Code or the Controlled Substances Act or any
6 other form of diversion, correct?

7 A. Correct.

8 MS. DESH: Okay. I think that's
9 all the questions that I have for you. Maybe
10 it would be a good time to take a short break,
11 and then if we have any other questioning, we
12 can follow up. Do you want to take ten
13 minutes?

14 THE WITNESS: Are these -- the
15 rest of these exhibits in the envelopes, are
16 those yours or --

17 MS. DESH: They are mine. I am
18 finished with them.

19 THE WITNESS: You're finished with
20 them?

21 MR. CIACCIO: Do any other defendants
22 know if they're -- is anybody definitely asking
23 more questions, CVS or Rite-Aid or anybody?

24 MR. NORTEY: Let's go off the
25 record.

1 THE VIDEOGRAPHER: Off the record,
2 3:37.

3 (Off the record.)

4 THE VIDEOGRAPHER: We're on the
5 record at 3:49.

6 EXAMINATION

7 BY MR. HERMAN:

8 Q. Agent Edwards, I'm Steve Herman.
9 I represent CVS, and I just have a few
10 questions for you; try to go through them
11 fairly quickly.

12 I take it from your testimony earlier
13 today that you've inspected CVS Pharmacies; is
14 that correct?

15 A. That's correct.

16 Q. And like with everyone else, when
17 you tried to do that, you tried to be thorough?

18 A. Yes.

19 Q. And if there was an issue, you
20 would document it in the inspection report?

21 A. Yes.

22 Q. Okay. Earlier today I think you
23 mentioned that Giant Eagle had an approved
24 software system. Do you recall that testimony?

25 A. Yes.

1 Q. Do you recall if CVS also had an
2 approved software system?

3 A. Yes.

4 Q. Okay. And when you say approved,
5 do you mean that it was approved by the Ohio
6 Board of Pharmacy?

7 A. Correct.

8 Q. And to your knowledge, has the
9 Ohio Board of Pharmacy ever denied a license
10 application for a CVS Pharmacy?

11 A. Not to my knowledge.

12 Q. Okay. To your knowledge, has Ohio
13 Board of Pharmacy ever denied the renewal of a
14 license for a CVS Pharmacy?

15 A. Not to my knowledge.

16 Q. To your knowledge, and based on
17 your inspections, did the CVS Pharmacies in
18 Lake and Trumbull County meet the requirement
19 for licenses?

20 A. Yes.

21 Q. To your knowledge, were
22 inspections at CVS Pharmacies generally
23 favorable and positive?

24 A. Generally, yes.

25 Q. To your knowledge, has the CVS

1 Pharmacy in Trumbull or Lake County ever had
2 its license revoked?

3 A. Not to my knowledge.

4 Q. To your knowledge, has the CVS
5 Pharmacy in Lake or Trumbull County ever had
6 its license suspended?

7 A. Not to my knowledge.

8 Q. Earlier today you mentioned that
9 you had told people occasionally something
10 along the lines of, if you don't write it down,
11 it didn't happen. Do you recall that
12 testimony?

13 A. I remember saying that, yes.

14 Q. Okay. Even if a pharmacist
15 doesn't document an action, would you agree
16 that the pharmacist could have actually
17 completed that action?

18 A. Yes.

19 Q. Okay. And is it fair to say that
20 you meant that documentation is a best
21 practice, because without documentation the
22 pharmacist may not be able to show he or she
23 took an action after the fact if someone
24 inquires?

25 A. That's correct.

1 Q. A couple times today you mentioned
2 how things have evolved over time. I just
3 wanted to talk with you about that briefly. I
4 think you testified that OARRS was created in
5 2006; is that correct?

6 A. Yes.

7 Q. And then later it became required
8 to check OARRS by pharmacists and prescribers
9 in certain circumstances?

10 A. Correct.

11 Q. And I think you mentioned that
12 over time the Board of Pharmacy had developed
13 some proactive reports. I believe you
14 mentioned 640 report; is that correct?

15 A. Correct.

16 Q. And do you recall that in 2011
17 Ohio passed a law that regulates pain
18 management clinics?

19 A. Yes.

20 Q. Are you familiar with the fact
21 that Ohio has put out prescribing guidelines,
22 various -- I believe they put one out in 2012.
23 Do you recall that?

24 A. Vaguely I recall that, yes.

25 Q. And then since that time, they've

1 put out additional prescribing guidelines for
2 prescription opioids. Do you recall that?

3 A. That sounds familiar.

4 Q. Is it fair to say that the way
5 that Ohio and the Ohio Board of Pharmacy have
6 addressed opioid abuse issues has evolved over
7 time?

8 A. Yes.

9 MR. HERMAN: Thank you. That's
10 all the questions I have for right now.

11 MR. CIACCIO: Plaintiffs aren't going
12 to have any questions. I think we're done.

13 THE REPORTER: Will the witness read
14 and sign?

15 MR. CIACCIO: The witness will read
16 and sign.

17 THE VIDEOGRAPHER: Off the record,
18 3:53.

19 (Deposition concluded at 3:53 p.m.)

20 * * *

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25

1 STATE OF OHIO)

2 COUNTY OF MONTGOMERY) SS: CERTIFICATE

3
4 I, Patti Stachler, RMR, CRR, a
5 Notary Public within and for the State of Ohio,
6 duly commissioned and qualified,

7 DO HEREBY CERTIFY that the
8 above-named TREY EDWARDS was by me first
9 remotely duly sworn to testify the truth, the
10 whole truth, and nothing but the truth.

11 Said testimony was reduced to
12 writing by me stenographically in the presence
13 of the witness and thereafter reduced to
14 typewriting.

15 I FURTHER CERTIFY that I am not a
16 relative or attorney of either party, in any
17 manner interested in the event of this action,
18 nor am I, or the court reporting firm with
19 which I am affiliated, under a contract as
20 defined in Civil Rule 28(D).

1 IN WITNESS WHEREOF, I have
2 hereunto set my hand and seal of office at
3 Dayton, Ohio, on this 15th day of December
4 2020.

5
6
7 
8

 PATTI STACHLER, RMR, CRR
9 NOTARY PUBLIC, STATE OF OHIO
 My commission expires 10-5-2023

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Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

December 16, 2020

To: Joseph L. Ciaccio, Esq.

Case Name: National Prescription Opiate Litigation - Track 3

Veritext Reference Number: 4366427

Witness: Trey Edwards Deposition Date: 12/11/2020

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4366427

CASE NAME: National Prescription Opiate Litigation - Track 3

DATE OF DEPOSITION: 12/11/2020

WITNESS' NAME: Trey Edwards

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

Date Trey Edwards

Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;

They signed the foregoing Sworn
Statement; and

Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4366427

CASE NAME: National Prescription Opiate Litigation - Track 3

DATE OF DEPOSITION: 12/11/2020

WITNESS' NAME: Trey Edwards

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Trey Edwards

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;

They have listed all of their corrections in the appended Errata Sheet;

They signed the foregoing Sworn Statement; and

Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

ASSIGNMENT NO: 4366427

Date _____ Trey Edwards
SUBSCRIBED AND SWORN TO BEFORE ME THIS _____
DAY OF _____, 20____.

Commission Expiration Date

[& - 2006]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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